Important Information: Prior to use, refer to the "Instructions for Use" supplied with the product for indications, contraindications, side effects, suggested procedure, warnings, and precautions.

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

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.

n-BCA will adhere to most surfaces. Avoid contact with non-disposable surfaces or surfaces that cannot be cleaned with acetone.

Prior to use, refer to the "Instructions for Use" supplied with the product for indications, contraindications, side effects, suggested procedure, warnings, and precautions.

Ethiodized Oil should NEVER be used as a radioopaque contrast agent to assess hemodynamics and should be used ONLY to prepare the TRUFILL® n-BCA Liquid Embolic System as a long-term implant.

The TRUFILL® n-BCA Liquid Embolic System is contraindicated when any of the following conditions exist:

- Intrathecally
- 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.
- Vasospasm stops blood flow.
- Therapeutic embolization should not be performed when high blood flow precludes safe infusion or where the catheter is not able to advance through the leak.
- 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.

Proper handling is required to avoid premature polymerization and occlusion of the delivery system or adherence of the catheter tip to the vessel wall.

AVM embolization may influence blood flow patterns, thereby subjecting arteries supplying the AVM to increased pressures. Increased arterial pressures could result in CVA (stroke), death, hemorrhage, hematoma, headache, infection/inflammation, neurological deficits, passage of embolic material into normal vessels adjacent to the lesion, arterial dissection, thromboembolism, occluded catheter, parenchymal hemorrhage, and arteriovenous malformations (AVMs) when pre-surgical devascularization is desired.

Ethiodized Oil may elute from the device over time.

Life threatening and fatal reactions may occur without warning. At all times a fully equipped emergency cart and resuscitation equipment should be readily available, and personnel competent in recognizing and treating reactions of all severity should be on hand.
CORDIS ENTERPRISE®
Vascular Reconstruction Device and Delivery System

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Contact your Sales Representative for pricing information.

Humanitarian Device (USA ONLY): The CORDIS ENTERPRISE® Vascular Reconstruction Device and Delivery System is authorized by Federal Law for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥ 2.5 mm and ≤ 4 mm. Wide-neck is defined as having a neck width ≥ 4 mm or a dome-to-neck ratio < 2. The effectiveness of this device for this use has not been demonstrated.
AGILITY® Steerable Guidewires

PRODUCT SPECIFICATIONS

- Outer Diameter: 0.010, 0.014, or 0.016 in.
- Taper Lengths: 33 - 45 cm
- Shaft Material: Stainless Steel
- Tip Coil Material: Platinum/Tungsten
- Tip Coil Length: 8 - 20 cm
- Usable Length: 145 - 205 cm
- Exchange Length (350 cm): 0.014 & 0.016 in.
- Coating: Hydrophilic
- Tip Style: Straight (Shapeable)

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Contact your Sales Representative for pricing information.
ESSENCE® Steerable Guidewires

PRODUCT SPECIFICATIONS

- Outer Diameters: 0.014/0.012, 0.014, 0.018 in.
- Taper Lengths: 26 - 32 cm
- Tip Shape: Straight (Shapeable)

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Contact your Sales Representative for pricing information.
**ENVOY® 5F Guiding Catheters**

**PRODUCT SPECIFICATIONS**

- Construction: Nylon/polyurethane stainless steel braid
- Outer Diameter: 5F
- Inner Diameter: 0.056 in.
- Inner Coating: PTFE

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Contact your Sales Representative for pricing information.
**PRODUCT SPECIFICATIONS**

- Construction: Nylon/polyurethane stainless steel braid
- Outer Diameter: 6F
- Inner Diameter: 0.070 in.
- Inner Coating: PTFE

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Contact your Sales Representative for pricing information.
PROWLER® SELECT® Microcatheters

**PRODUCT SPECIFICATIONS**

- **Construction:** Proprietary braid / coil reinforced technology
  - Proximal braided shaft
  - Distal reinforced coil
- **Inner Coating:** PTFE liner hub to tip
- **Outer Coating:** Hydrophilic
- **Hub Material:** Nylon
- **Max. Guidewire:**
  - PROWLER® SELECT® LP-ES Microcatheter 0.014 in.
  - PROWLER® SELECT® Plus Microcatheter 0.018 in.
- **Min. Guiding Catheter ID:**
  - PROWLER® SELECT® LP-ES Microcatheter 0.035 in.
  - PROWLER® SELECT® Plus Microcatheter 0.042 in.

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Contact your Sales Representative for pricing information.
# PROWLER® Microcatheters

## PRODUCT SPECIFICATIONS

- **Construction:** Proprietary braid / coil reinforced technology
  - Proximal braided shaft
  - Distal reinforced coil
- **Inner Coating:** PTFE liner hub to tip
- **Outer Coating:** Hydrophilic
- **Hub Material:** Nylon
- **Max. Guidewire:**
  - PROWLER® 10 Microcatheter: 0.012 in.
  - PROWLER® 14 Microcatheter: 0.014 in.
  - PROWLER® Plus Microcatheter: 0.018 in.
- **Min. Guiding Catheter ID:**
  - PROWLER® 10 and PROWLER® 14 Micro.: 0.035 in.
  - PROWLER® Plus Microcatheter: 0.042 in.

## Table

<table>
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<tr>
<th>UPN</th>
<th>Catalog No.</th>
<th>Usable Length (cm)</th>
<th>Total Length (cm)</th>
<th>Distal Length (cm)</th>
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<th>Inner Diameter (in.)</th>
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Contact your Sales Representative for pricing information.
**RAPIDTRANSIT® Microcatheters**

**PRODUCT SPECIFICATIONS**

- Construction: Proprietary braid / coil reinforced technology
  - Proximal braided shaft
  - Distal reinforced coil
- Outer Diameter (proximal): 2.8F
- Outer Diameter (distal): 2.3F
- Inner Diameter: 0.021 in.
- Inner Coating: PTFE
- Outer Coating: Hydrophilic
- Hub Material: Nylon
- Max. Guidewire: 0.018 in.

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<th>UPN</th>
<th>Catalog No.</th>
<th>Usable Length (cm)</th>
<th>Total Length (cm)</th>
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Contact your Sales Representative for pricing information.
### PRODUCT SPECIFICATIONS

- Construction: Proprietary braid / coil reinforced technology
  - Proximal braided shaft
  - Distal reinforced coil
- Outer Diameter (proximal): 2.8F
- Outer Diameter (distal): 2.5F
- Inner Diameter: 0.021 in.
- Inner Coating: PTFE
- Outer Coating: Hydrophilic
- Hub Material: Nylon
- Max. Guidewire: 0.018 in.
- Distal Flexible Length: 30 cm

### TABLE

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Contact your Sales Representative for pricing information.
MASSTRANSIT® Microcatheters

PRODUCT SPECIFICATIONS

• Construction: Proprietary braid / coil reinforced technology
  Proximal braided shaft
  Distal reinforced coil
• Outer Diameter (proximal): 2.8F
• Outer Diameter (distal): 2.7F
• Inner Diameter: 0.027 in.

• Inner Coating: PTFE
• Outer Coating: Hydrophilic
• Max. Guidewire: 0.018 in.
• Max. PVA: 2,000 microns
• Embolic Coil Range: 0.018 - 0.025 in.

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<th>Catalog No.</th>
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*K refers to kits that include an ESSENCE® 18 Guidewire and an Adjustable Hemostasis Valve.

Contact your Sales Representative for pricing information.
### TRUFILL® Pushable Coils

**PRODUCT SPECIFICATIONS**

- Wire Material: Platinum
- Fiber: Nylon
- Coil Outer Diameter: 0.014 in.
- Microcatheter: 0.021 in. ID

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<th>Size (cm)</th>
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Packaged five (5) coils per box. Each coil is supplied in a transparent nylon introducer with stylet.

Contact your Sales Representative for pricing information.

### TRUPUSH® Coil Pusher

**PRODUCT SPECIFICATIONS**

- Construction: Nitinol core-to-tip design, with dual tip markers
- Overall Length: 195 cm
- Taper Length: 50 cm
- Outer Diameter (proximal): 0.016 in.
- Outer Diameter (distal): 0.017 in.
- Coating: PTFE coated taper
- Microcatheter: 0.021 in. ID

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Contact your Sales Representative for pricing information.
## MINI COMPLEX

### PRODUCT SPECIFICATIONS
- Wire Material: Platinum / Tungsten
- Wire Diameter: 0.002 in. Fill
- Coil Outer Diameter: 0.012 in.

### PRODUCT SPECIFICATIONS

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Contact your Sales Representative for pricing information.
# TRUFILE DCS ORBIT™ Detachable Coils

## COMPLEX

**PRODUCT SPECIFICATIONS**
- Wire Material: Platinum / Tungsten
- Wire Diameter: 0.002 in. Fill; 0.003 in. Standard
- Coil Outer Diameter: 0.012 in.

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Contact your Sales Representative for pricing information.
**PRODUCT SPECIFICATIONS**

- Wire Material: Platinum / Tungsten
- Wire Diameter: 0.002 in. Fill / 0.003 in. Standard
- Coil Outer Diameter: 0.012 in.

### PRODUCT SPECIFICATIONS TABLE

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Contact your Sales Representative for pricing information.
### PRODUCT SPECIFICATIONS

- Wire Material: Platinum / Tungsten
- Wire Diameter: 0.002 in. Fill
- Coil Outer Diameter: 0.012 in.

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Contact your Sales Representative for pricing information.
TRUFILL® n-BCA Liquid Embolic System

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See facing page for Essential Prescribing Information (EPI)
CORDIS ENTERPRISE® Vascular Reconstruction Device and Delivery System

Essential Prescribing Information (EPI)

Humanitarian Device (USA ONLY)
The CORDIS ENTERPRISE® Vascular Reconstruction Device and Delivery System is authorized by Federal Law for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥ 2.5 mm and ≤ 4 mm. Wide-neck is defined as having a neck width ≥ 4 mm or a dome-to-neck ratio < 2. The effectiveness of this device for this use has not been demonstrated.

Intended Use / Indications
The CORDIS ENTERPRISE® Vascular Reconstruction Device and Delivery System is intended for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥ 2.5 mm and ≤ 4 mm. Wide-neck is defined as having a neck width ≥ 4 mm or a dome-to-neck ratio < 2.

Contraindications
Intracranial artery stenting is generally contraindicated in the following patient types:
• Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
• Patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to conditions such as:
  – Severe intracranial vessel tortuosity or stenoses
  – Intracranial vasospasm not responsive to medical therapy

Warnings
• The stenting procedure should be carried out under the direction of personnel with the requisite interventional training, especially intracranial stent procedures. Appropriate facilities should be available for managing the potential complications of the procedure.
• The device is designed to be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of resistance before proceeding.
• The appearance of the temperature exposure indicator label, found on the inner pouch, must be lighter than the surrounding gray color box. The acceptance criterion of the label is delineated by the graphic with the green check mark. Do not use if the temperature exposure indicator label is as dark or darker than the surrounding gray color box because the unconstrained stent diameter may have been compromised by exposure to high temperature. The reject criterion for the label is delineated by the graphics marked with a red “X”.
• Do not use if the inner package is opened or damaged.
• Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
• Adverse events may occur without warning. At all times a fully equipped emergency cart and resuscitation equipment should be readily available, and personnel competent in recognizing and treating adverse events of any severity should be on hand.

Precautions
• Experience with stent implants indicates that there is a risk of stenosis. Stenosis may require dilatation of the vessel segment containing the stent. The risks and long-term outcome following dilatation of endothelialized stents is unknown at present.
• The CORDIS ENTERPRISE® Vascular Reconstruction Device and Delivery System is not intended for use as a stand-alone device, i.e. without subsequent coil embolization of the aneurysm.
• Do not use the CORDIS ENTERPRISE® Vascular Reconstruction Device and Delivery System if any component appears damaged or missing.
• Confirm that the device labeling clearly indicates the size of the stent to be used.
• Do not expose the system to organic solvents (e.g., alcohol).
• For single use only. Do not resterilize or reuse.
• Use product prior to the “Use By” date.
• Store system in a cool, dark, dry place.
• Dispose of all used devices in accordance with hospital policy for biohazardous materials.
• Coil protrusion during embolization may not be visualized fluoroscopically because of the superimposition of the stent and coil mass. Intermittent angiograms in multiple views may be necessary to ensure there are no coil loops protruding into the parent artery.
• Do not recapture the stent more than once.
• During deployment, the stent may foreshorten. Refer to the “Device Description” section to examine foreshortening values for each of the stent sizes.
• The performance and safety of two or more overlapped stents has not been established. The ability of the stent to withstand post balloon dilatation has not been established.
• Select a stent length that is at least 10 mm longer than the aneurysm neck to maintain a minimum of 5 mm on either side of aneurysm neck.
• Use caution when crossing the deployed stent with guidewires or accessory devices.

Potential Adverse Events
Adverse events that may be associated with the use of the CORDIS ENTERPRISE® Vascular Reconstruction Device and Delivery System in the intracranial arteries include:

Allergic reaction including, but not limited to contrast, Nitinol metal and medications
Aneurysm recanalization
Arrhythmia
Arteriovenous fistula
Cerebral infarct
Coil migration/prolapse into normal vessels adjacent to the aneurysm
Craniocerebral hemorrhage
Death
Dissection

Emboli (air, tissue or thrombotic)
Emergent neurosurgery
Failure to deliver stent
Gore hemorrhage
Hematoma
Incomplete aneurysm occlusion
Infection
Ischemia
Injury to normal vessels or tissue
Intracerebral hemorrhagic
Myocardial infarction
Neurological deficit
Occlusion of side branch
Pain and/or infection at insertion site

Perforation
Pseudoaneurysm
Renal failure
Rupture, vessel or aneurysm
Seizures
Stenosis of stented segment
Stent migration/embolization
Stent thrombosis/occlusion
Stroke
TIA (transient ischemic attack)
Total occlusion of treated segment
Vasospasm
Vessel thrombosis
AGILITY® Steerable Guidewires
Essential Prescribing Information (EPI)

Intended Use / Indications
The Cordis Neurovascular AGILITY® Steerable Guidewires are intended for selective placement of microcatheters and other devices in the neuro and peripheral vasculature.

Contraindications
AGILITY® Steerable Guidewires are contraindicated for use in chronic total occlusions in the peripheral vasculature.

Warnings
Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. All parts are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Guidewires are delicate instruments and should be handled carefully. Special care should be taken when shaping the guidewire tip in order to prevent damage. Prior to use and when possible during the procedure, inspect the guidewire carefully for coil separation, bends, or kinks. Do not use a guidewire that shows signs of damage. Damage will prevent the guidewire from performing with accurate torque response and control.

- Guidewire manipulation/torquing should always be performed under fluoroscopic guidance.
- Never advance, withdraw or auger the guidewire against resistance without first determining the cause of resistance under fluoroscopy. Torquing the guidewire against resistance may cause damage and/or fracture which may result in separation of the distal tip.
- Should the guidewire tip become entrapped within the vasculature (i.e., small side branch), DO NOT TORQUE THE GUIDEWIRE. Advance the microcatheter distally, gently pull the guidewire back into the microcatheter, and remove the microcatheter/guidewire system as a unit.
- Should torque control/tip response be compromised during use, confirm tip integrity using fluoroscopy. LOSS OF TORQUE CONTROL MAY BE DUE TO CORE WIRE FRACTURE. Under fluoroscopic guidance, advance the microcatheter to the distal end of the guidewire and remove the microcatheter/guidewire system as a unit.
- The steerable guidewire should not be used during magnetic resonance procedures.

Precautions
- Store in a cool, dark, dry place.
- Do not use open or damaged packages.
- Use prior to the “Use By” date.
- Do not autoclave. Exposure to temperatures above 54°C (130°F) may damage the guidewire.
- Do not expose to organic solvents.
- Movement of torque device or metal insertion tool on a guidewire’s coating may compromise the integrity of the coating.

Complications
Procedures requiring percutaneous guidewire introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during or after the procedure.

Possible complications include, but are not limited to:
- infection
- hemorrhage
- emboli
- vasospasm
- perforation of the vessel wall
- ischemia and related neurological dysfunction, stroke and death
- dissection of the vessel wall
ESSENCE® Steerable Guidewires
Essential Prescribing Information (EPI)

**Intended Use / Indications**
The Cordis Neurovascular ESSENCE® Steerable Guidewires are intended for the introduction and positioning of interventional devices within the coronary, peripheral, and neuro vasculature.

**Contraindications**
The Cordis Neurovascular ESSENCE® Steerable Guidewires are contraindicated for use in chronic total occlusions. Contraindications for interventional devices are described in the instructions supplied with the respective device.

**Warnings**
Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. All parts are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Guidewires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guidewire carefully for coil separation, bends, or kinks. Do not use a guidewire that shows signs of damage.

- Damage will prevent the guidewire from performing with accurate torque response and control.
- Guidewire manipulation/torquing should always be performed under fluoroscopic guidance.
- Never advance, withdraw or auger the guidewire against resistance without first determining the cause of resistance under fluoroscopy. Torquing the guidewire against resistance may cause damage and/or fracture which may result in separation of the distal tip.
- Should the guidewire tip become entrapped within the vasculature (i.e., small side branch, tight stenosis), DO NOT TORQUE THE GUIDEWIRE. Advance the balloon catheter distally, gently pull the guidewire back into the balloon catheter, and remove the balloon catheter/guidewire system as a unit.
- Should torque control/tip response be compromised during use, confirm tip integrity using fluoroscopy. LOSS OF TORQUE CONTROL MAY BE DUE TO CORE WIRE FRACTURE. Under fluoroscopic guidance, advance the balloon catheter to the distal end of the guidewire and remove the balloon catheter/guidewire system as a unit.

**Precautions**
- Store in a cool, dark, dry place.
- Do not use open or damaged packages.
- Use prior to the “Use By” date.
- Do not autoclave. Exposure to temperatures above 54°C (130°F) may damage the guidewire.
- Do not expose to organic solvents.
- Movement of torque device or metal insertion tool on a guidewire’s coating may compromise the integrity of the coating.

**Complications**
Procedures requiring percutaneous guidewire introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during or after the procedure.

Possible complications include, but are not limited to:
- air embolism
- hematoma at the puncture site
- infection
- perforation of the heart or vessel wall
- Tip Fractures have been reported in procedures involving total occlusions, highly tortuous vasculature and small side branches. For guidewire tip retrieval, please refer to the referenced publications for recommended techniques.
ENVOY® Guiding Catheters

Essential Prescribing Information (EPI)

Intended Use / Indications
The ENVOY® Guiding Catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

Contraindications
None known.

Warnings
Discard the guiding catheter after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Do not use with Ethiodol or Lipiodol* contrast media, or other such contrast media which incorporates the components of these agents.

Precautions
- Store in a cool, dark, dry place.
- Do not use open or damaged packages.
- Use prior to the “Use By” date.
- Exposure to temperatures above 54°C (130°F) may damage the catheter.
- Do not expose to organic solvents.
- Inspect the guiding catheter before use to verify that its size, shape, and condition are suitable for the specific procedure.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause for the resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the catheter.
- Extreme care must be taken to avoid damage to the vasculature through which the catheter passes. The guiding catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.
- Torquing the catheter excessively while kinked may cause damage which could result in possible separation along the catheter shaft. Should the guiding catheter shaft become severely kinked, withdraw the entire system (guiding catheter, guidewire, and catheter sheath introducer).
- Advancement, manipulation, and withdrawal of the guiding catheter should always be performed under fluoroscopic guidance.

Complications
Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to the following:
- air embolism
- hematoma at the puncture site
- infection
- perforation of the heart or vessel wall
**Intended Use / Indications**

The Cordis Neurovascular Infusion Catheters are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems outlined in Table 1 and for superselective angiography of the peripheral and coronary vasculatures. All agents must be used in accordance with manufacturer’s instructions for use.

**TABLE 1: Vascular Indications**

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It is recommended that the Cordis Neurovascular Infusion Catheters be used with a guiding catheter, a compatible catheter sheath introducer, and a steerable guidewire.

**Contraindications**

None known.

**Warnings**

THIS DEVICE IS INTENDED FOR ONE USE ONLY. Discard the infusion catheter after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Never advance or withdraw an intraluminal device against resistance until the cause of resistance is determined by fluoroscopy. If the cause cannot be determined, withdraw the catheter. Movement against resistance may result in damage to the vessel.

The infusion pressure should not exceed the maximum listed pressure for each catheter, as indicated in the flowrate charts. Pressure in excess of the recommended range may result in catheter rupture or tip severance.

**Precautions**

- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to the “Use By” date.
- Read and follow the “Instructions for Use” of all agents or contrast media used with the infusion catheters.

**Complications**

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications, which may occur during or after the procedure.

Possible complications include, but are not limited to the following:

- embolism
- hematoma at the punctured site
- infection
- dissection
- perforation of vessel wall
- distal embolization
TRUFILL® Pushable Coils
Essential Prescribing Information (EPI)

Intended Use / Indications
Pushable coils may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Contraindications
The use of pushable coils is contraindicated when any of the following conditions exist:
- When superselective placement is not possible.
- When the arteries supplying the lesion are not large enough to accept emboli.
- When patent extra-to-intracranial anastomoses are present.
- When end arteries lead directly to cranial nerves.
- When the A-V shunt is bigger than the size of the pushable coil.
- When there is severe atheromatous disease.
- When in the presence or likely onset of vasospasm.

Warnings
Performing therapeutic embolizations to occlude blood vessels is a high-risk procedure. The procedure should be carried out under the direction of personnel with the requisite interventional training and thorough knowledge of angiographic techniques, especially coil embolization techniques. Appropriate facilities should be available for coping with the potential complications of the procedure.

Contaminants found in the angiography room may cause foreign body reactions or infection. The physician must use the utmost caution to avoid introducing contaminants. Incomplete occlusion of vascular bed or territories may give rise to hemorrhage, ischemia, infarction, development of alternative vascular pathways, or recurrence of symptoms. Do not reuse. Discard after one procedure.

Precautions
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Use prior to the “Use By” date.
- Angiography is necessary for the pre-embolization evaluation, operative control and post-embolization follow-up.
- Ensure proper selection of pushable coil size according to vascular territory and measurements taken from a baseline angiogram.
- Required additional items: appropriate sized guiding catheter to facilitate TRANSIT® catheter access to the intended vasculature. Continuous flush setup with two rotating hemostatic valves, three bags of appropriate flush, one 3-way stopcock, and one 1-way stopcock.
- Pushable coils should be delivered through a micrcatheter with a minimum I.D. of .021 in. (0.5 mm), such as the TRANSIT® Infusion Catheter Product Line. The pushable coils are designed to be delivered using the Cordis Neurovascular Coil Pusher. Compatibility of the Cordis Neurovascular Pushable Coil with other catheters and with other coil delivery devices has not been established.

Complications
Vascular occlusion procedures should not be attempted by physicians unfamiliar with all possible complications. Complications specific to embolization procedures may occur at any time during or after the procedure and may include, but are not limited to, the following:
- Ischemia at an undesired location
- Stroke or cerebral infarction
- Pushable coil migration into normal vessels adjacent to the lesion
- Pulmonary embolism
- Vessel dissection, perforation, rupture and hemorrhage
- Neurological deficits
- Injury to normal vessels or tissue
- Infection
- Allergic reaction
- Vasospasm
- Death
TRUFILL DCS ORBIT™ Detachable Coils

Essential Prescribing Information (EPI)

Intended Use / Indications
The TRUFILL DCS ORBIT™ Detachable Coil is indicated for embolizing certain intracranial aneurysms that, because of their morphology, location, or the patient's general medical condition, are considered by the treating neurosurgical team to be:
1. very high-risk for management by traditional operative techniques;
2. inoperable and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The TRUFILL DCS ORBIT™ Detachable Coil is also intended for arterial and venous embolization in the peripheral vasculature.

Contraindications
The use of the TRUFILL DCS ORBIT™ Detachable Coil is contraindicated when:
• superselective placement is not possible
• the arteries supplying the lesion are not large enough to accept embolic material
• patent extra-to-intracranial anastomoses are present
• end arteries lead directly to cranial nerves
• the A-V shunt is bigger than the size of the coil
• there is severe atheromatous disease
• in the presence or likely onset of vasospasm

Warnings
Therapeutic embolizations to occlude blood vessels are high-risk procedures. The procedure should be carried out under the direction of personnel with the requisite interventional training and thorough knowledge of angiographic techniques, especially coil embolization techniques. Appropriate facilities should be available for managing the potential complications of the procedure.

• Contaminants found in the angiography room may cause foreign body reactions or infection. The physician must use the utmost caution to avoid introducing contaminants.
• Incomplete occlusion of vascular bed or territories may give rise to hemorrhage, ischemia, infarction, development of alternative vascular pathways, or recurrence of symptoms.
• Do not use any other syringes other than the specified TRUFILL® DCS Syringe or TRUFILL® DCS Syringe II for operation of the TRUFILL DCS ORBIT™ Detachable Coil.
• The introduction of air emboli may occur during detachment if one of the following is not performed properly:
  - saline purge of the syringe to remove all air prior to connecting to the delivery tube hub.
  - saline purge of the delivery tube with visual confirmation at the hub.
  - saline flush of the delivery tube hub prior to any system reconnections.
• Do not use the distal tip of the infusion catheter to manipulate or reposition embolic coils previously detached in the patient’s vasculature.
• Do not reuse. Discard after one procedure.
• Failure to open the second RHV sufficiently prior to slow and careful removal of the delivery tube from the patient could result in damage to the distal portion of the delivery tube.

Precautions
TRUFILL DCS ORBIT™ Detachable Coils are delicate devices and should be handled carefully. Prior to use and when possible during the procedure, inspect the system for bends or kinks. Do not use a coil system that shows signs of damage.

• Do not expose the product to organic solvents.
• The long-term effects of this product on extravascular tissues have not been established, so care should be taken to retain this device in the intravascular space.
• Multiple embolization procedures may be required to achieve the desired occlusion of some vessels or aneurysms.
• The TRUFILL DCS ORBIT™ Detachable Coil is intended for one use only. Do not resterilize and/or reuse the device.
• After use, dispose in accordance with hospital, administrative and/or local government policy.
• Store in a cool, dark, dry place.
• Do not use if package is open or damaged.
• Use prior to the “Use By” date.
• Angiography is necessary for the pre-embolization evaluation, operative control, and post-embolization follow up.
• Ensure proper detachable coil selection according to vascular territory and measurements taken from a baseline angiogram.

Adverse Events
Complications specific to embolization procedures may occur at any time during or after the procedure and may include, but are not limited to, the following:
• ischemia at an undesired location
• stroke or cerebral infarction
• coil migration into normal vessels adjacent to the lesion
• pulmonary embolism
• vessel dissection, perforation, rupture and hemorrhage
• neurological deficits
• injury to normal vessels or tissue
• infection
• allergic reaction
• vasospasm
• death

Precautions
TRUFILL DCS ORBIT™ Detachable Coils are delicate devices and should be handled carefully. Prior to use and when possible during the procedure, inspect the system for bends or kinks. Do not use a coil system that shows signs of damage.

• Do not expose the product to organic solvents.
• The long-term effects of this product on extravascular tissues have not been established, so care should be taken to retain this device in the intravascular space.
• Multiple embolization procedures may be required to achieve the desired occlusion of some vessels or aneurysms.
• The TRUFILL DCS ORBIT™ Detachable Coil is intended for one use only. Do not resterilize and/or reuse the device.
• After use, dispose in accordance with hospital, administrative and/or local government policy.
• Store in a cool, dark, dry place.
• Do not use if package is open or damaged.
• Use prior to the “Use By” date.
• Angiography is necessary for the pre-embolization evaluation, operative control, and post-embolization follow up.
• Ensure proper detachable coil selection according to vascular territory and measurements taken from a baseline angiogram.

Adverse Events
Complications specific to embolization procedures may occur at any time during or after the procedure and may include, but are not limited to, the following:
• ischemia at an undesired location
• stroke or cerebral infarction
• coil migration into normal vessels adjacent to the lesion
• pulmonary embolism
• vessel dissection, perforation, rupture and hemorrhage
• neurological deficits
• injury to normal vessels or tissue
• infection
• allergic reaction
• vasospasm
• death
TRUFILL® DCS Syringe II

Essential Prescribing Information (EPI)

Intended Use / Indications
The TRUFILL® DCS Syringe II is indicated for use with the TRUFILL® family of Detachable Coils.

Contraindications
The TRUFILL® DCS Syringe II should only be used with the TRUFILL® family of Detachable Coils. Refer to the “Instructions for Use” for the TRUFILL® family of Detachable Coils for additional contraindications.

Warnings
• Do not reuse. Discard after a single clinical procedure.
• Only use with sterile saline solution. Contrast solutions or other solutions should not be used with this syringe.
• Refer to the “Instructions for Use” for the TRUFILL® family of Detachable Coils for additional warnings.

Precautions
• Store in a cool, dark, dry place.
• Do not use if sealed plastic tray is opened or damaged.
• Use prior to the “Use By” date.
• Pressures should be closely monitored when using the TRUFILL® family of Detachable Coils. The syringe is a high volume, low compliance device capable of generating high pressures with relative ease.
• Exceeding zone #3 (green zone) could cause syringe damage. If zone #3 is exceeded, the syringe should not be reused for additional coil detachments.
• The TRUFILL® DCS Syringe II can be safely used up to 5 coil detachments, or attempted coil detachments during a single clinical procedure.
• Refer to the “Instructions for Use” for the TRUFILL® family of Detachable Coils for additional precautions.

Adverse Events
Refer to the “Instructions for Use” for the TRUFILL® family of Detachable Coils for potential adverse events.
**TRUFLIL® n-BCA Liquid Embolic System**

**Essential Prescribing Information (EPI)**

**Intended Use / Indications**

The TRUFLIL® 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 TRUFLIL® n-BCA Liquid Embolic System is contraindicated. These components must be used as a system.

TRUFLIL® Embolized Oil alone should not be injected.

- Intravascularly
- Intrathecally
- Intrabronchially

The use of the TRUFLIL® n-BCA Liquid Embolic System is contraindicated when any of the following conditions exist:

- Optic nerve or other vital structures are not visible through the needle or catheter tip.
- A previous history of reaction to cyanoacrylates exists.
- A previous history of neurovascu lar accident exists.
- An allergic reaction or intolerance to the occlusion procedure is anticipated.
- Intravascular Hemorrhage

**Warnings**

The safety and effectiveness of the TRUFLIL® 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.

Fluoroscopic determination of the adequacy of the TRUFLIL® n-BCA Liquid Embolic System by comparison with a similar syringe containing contrast material is essential. Fluoroscopic visualization of the TRUFLIL® n-BCA System may cause inappropriate embolization.

TRUFLIL® n-BCA is a fast setting adhesive capable of adhering to most body 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.

TRUFLIL® Embolized Oil should NEVER be used as a radio opaque contrast agent to assess hemorrhage and should be used ONLY to prepare the TRUFLIL® n-BCA Liquid Embolic System for use. TRUFLIL® Embolized Oil is not recommended for use in the catheter tip of the device or in the delivery system. TRUFLIL® n-BCA Liquid Embolic System is intended to be used for AVM embolization.

- Optimal catheter placement is not possible.
- A previous history of reaction to cyanoacrylates exists.
- An allergic reaction or intolerance to the occlusion procedure is anticipated.
- Intravascular Hemorrhage

**Adverse Events**

- Early Polymerization
- Inability to subselect vessel
- Death
- Hematoma
- Headache
- Infection/Inflammation
- Tracheal occlusion
- Tracheal obstruction
- AVM Rupture
- Seizure
- Catheter glued inside vessel
- Late Polymerization
- Occluded Catheter
- Parenchymal hemorrhage
- Vasospasm
- Pulmonary embolism
- Allergic reaction

**Procedures**

- Blood in a cool, dark place.
- Do not use in package, on open or damaged.
- Use prior to “Use by” date
- Sterility is necessary for pre-embolization evaluation, operative control and post-embolization follow-up.
- Verify that the TRUFLIL® 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 TRUFLIL® n-BCA into an appropriate injection syringe.
- TRUFLIL® n-BCA will adhere to most surfaces. Avoid contact with non-disposable surfaces or distilled water.
- Gloves and surface protection are recommended when handling TRUFLIL® n-BCA.
- Make sure the catheter and accessories used in direct contact with the TRUFLIL® 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.

- TRUFLIL® n-BCA Liquid Embolic System is not be advance or advanced undertreatment.

• Store in a cool, dark, dry place.
• Do not use if package is open or damaged.
• Angiography is necessary for pre-embolization evaluation, operative control and post-embolization follow-up.
• Verify that the TRUFLIL® 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 TRUFLIL® n-BCA into an appropriate injection syringe.
• TRUFLIL® n-BCA will adhere to most surfaces. Avoid contact with non-disposable surfaces or distilled water.
• Gloves and surface protection are recommended when handling TRUFLIL® n-BCA.
• Make sure the catheter and accessories used in direct contact with the TRUFLIL® 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.

- TRUFLIL® n-BCA Liquid Embolic System is contraindicated when any of the following conditions exist:

- A previous history of reaction to cyanoacrylates exists.
- An allergic reaction or intolerance to the occlusion procedure is anticipated.
- Intravascular Hemorrhage

**Instructions for Use**

- 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 TRUFLIL® n-BCA into an appropriate injection syringe.

- TRUFLIL® n-BCA Liquid Embolic System is contraindicated when any of the following conditions exist:

- Optic nerve or other vital structures are not visible through the needle or catheter tip.
- A previous history of reaction to cyanoacrylates exists.
- A previous history of neurovascular accident exists.
- An allergic reaction or intolerance to the occlusion procedure is anticipated.
- Intravascular Hemorrhage

**Family of Products**

A complete line of neurovascular intervention products.
Important Information:

- For a complete list of products not represented here, please contact your Cordis Neurovascular representative.
- Miami Lakes, FL  33014
- Cordis Neurovascular, Inc.

Caution:

- Indications, contraindications, side effects, suggested procedure, warnings, and precautions.

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

- Early Polymerization
- Inability to subselect vessel
- CVA (stroke)
- Death
- Hemorrhage
- Incorrect vessel(s) occluded
- Infection/Inflammation

- Seizure
- Catheter glued inside vessel
- Occluded Catheter
- Parenchymal hemorrhage
- Occlusion
- Vasospasm
- Pulmonary embolism
- Allergic reaction
- AVM Rupture
- Contrast Agent for diagnostic use only

- 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 is clean.
- n-BCA Liquid Embolic System is contraindicated when any of the following conditions exist:
  - 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.
  - A previous history of reactions to contrast agents exists.
  - Optimal catheter placement is not possible.
  - Intravascularly
  - Intrathecally
  - Intrabronchially
  - Separation of the individual components of the TRUFILL® n-BCA Liquid Embolic System is contraindicated. These components must be used as a system.

- TRUFILL® n-BCA Liquid Embolic System is indicated for the embolization of cerebral arteriovenous malformations (AVMs) when pre-surgical devascularization is desired.

- 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.
- Refer to “Accessories” under the “Recommended Procedure” section of the instructions.
- TRUFILL® n-BCA Liquid Embolic System is a family of products.
- Cordis Neurovascular, Inc. Family of Products
- A complete line of neurovascular intervention products.

- Do not use with any device containing polycarbonate. Cyanoacrylates cause polymers containing polycarbonate to degrade with contact.
- TRUFILL® n-BCA is a fast-setting adhesive capable of adhering to most body tissues.
- Ethiodized Oil should NEVER be used as a radio opaque contrast agent to assess intravascular contrast.
- Ethiodized Oil may elute from the device.
- Laboratory studies have determined that TRUFILL® n-BCA Liquid Embolic System may influence blood flow patterns, thereby subjecting arteries supplying the AVM to increased pressures. Increased arterial pressures could result in hemorrhagic complications.
- Performing therapeutic embolizations to occlude blood vessels is a high risk procedure.
- Therapeutic embolization should not be performed when high blood flow precludes safe infusion or fluoroscopic determination of the radiopacity of the TRUFILL® n-BCA mixture may cause inappropriate embolization.
- Life-threatening and fatal reactions may occur without warning. At all times a fully equipped emergency cart and resuscitation equipment should be readily available, and personnel competent in recognizing and treating reactions of all severity should be on hand.
- TRUFILL® n-BCA Liquid Embolic System is a family of products.
- Cordis Neurovascular, Inc. Family of Products
- A complete line of neurovascular intervention products.