CerebroFlo™ EVD Catheter Set

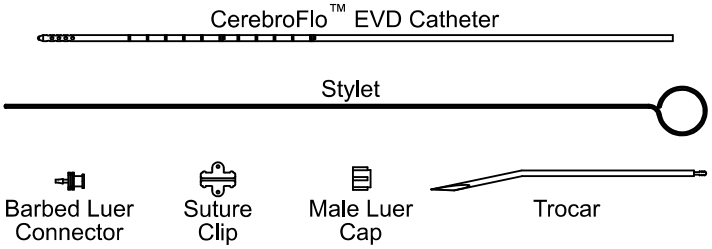
External Ventricular Drainage Catheter with Endexo™ [1] Technology

Catalog Number 37.550.101

Description of the CerebroFlo™ EVD Catheter

The CerebroFlo™ EVD Catheter is a 3.3 mm diameter (10 Fr.), 35 cm long polyurethane catheter for diverting cerebrospinal fluid (CSF) from the ventricles of the brain through a series of drainage holes near the catheter's bullet shaped tip. The catheter is barium sulfate impregnated to provide radiopacity. Black stripes are located every 1 cm between 5 cm and 15 cm from the catheter tip. Double stripes and numerical markings are located at 10 cm and 15 cm (all dimensions are nominal).

To facilitate introduction of the catheter into the lateral ventricle, the catheter is packaged with a stainless-steel stylet inserted into the catheter lumen. A trocar is supplied with the catheter to facilitate subcutaneous tunneling away from the burr hole. The external portion of the catheter may be secured to the scalp by the radiopaque suture clip. The barbed luer connector supplied with each CerebroFlo™ EVD Catheter will connect the catheter to external drainage systems. The included male luer cap may be used to cap barbed luer connector until the catheter is connected to a drainage or monitoring device.



Indications For Use

The CerebroFlo™ EVD Catheter is indicated for temporary insertion into a ventricular cavity of the brain for external drainage of cerebrospinal fluid (CSF) in those patients with elevated intracranial pressure (ICP), intraventricular hemorrhage, or hydrocephalic shunt infections.

Instructions for Use for the CerebroFlo™ EVD Catheter

1. Placement of the catheter may be accomplished through a variety of surgical techniques; therefore, the surgeon is best advised to use the method which his/her own practice and training dictate to be best for the patient. With the stylet completely inserted into the catheter lumen, introduce and position the CerebroFlo™ EVD Catheter into the ventricle.
2. Verify the placement of the catheter in the ventricle.
3. The surgeon may insert the barbed end of the trocar into the catheter and tunnel subcutaneously with the trocar, using his/her preferred surgical technique. Remove the trocar from the catheter.
4. Fully insert the barbed end of the luer connector into the catheter. The catheter tubing may be carefully secured to the connector with ligatures in such a manner as to avoid cutting or nicking of the tubing.
5. Check for free flow of CSF and then cap the luer connector with the included luer cap until the catheter is connected to a drainage or monitoring device.
6. Spread open the suture clip, and place around the catheter at the desired position. Secure the suture clip to the catheter with ligatures in such a manner as to avoid cutting or nicking of the tubing. Suture the clip to an intact portion of the scalp.
7. Follow the instructions included with the drainage and/or ICP monitoring system for recommended drainage procedures.
8. The CerebroFlo™ EVD Catheter and Suture clip should be removed as soon as the clinical situation allows.

Contraindications

This device is not designed, sold or intended for use except as indicated.

The ventricular catheter is contraindicated if scalp infection is present. A patient undergoing external drainage and monitoring must be kept under continuous, close supervision. The use of a ventricular drainage catheter is contraindicated where trained personnel are not available to supervise monitoring and drainage on a 24-hour-a-day basis.

The ventricular catheter is contraindicated for use longer than 21 days.

Insertion of the ventricular catheter is contraindicated in patients with coagulopathy due to prior administration of anticoagulants or antithrombotic, or who are known to have a bleeding diathesis. Coagulopathy should be corrected according to institutional protocols before insertion of an EVD.

Warnings and Precautions

Prior to surgery, the surgeon should inform the prospective patient and/or their representatives of the warnings, precautions, and possible complications associated with this product.

Use of the ventricular catheter should be considered with extreme caution for patients taking anti-platelet medications.

Improper use of instruments in the handling, insertion, tunneling or repositioning of the catheter may result in nicks, tears, punctures, slitting, breakage, or crushing of the CerebroFlo™ EVD components. Such damage may lead to device failure, potentially requiring device removal and replacement.

Proper aseptic technique must be followed, and care taken to prevent the introduction of foreign material onto or into the catheter. Such foreign material may result in obstruction of the catheter, foreign body reactions, allergic reactions, or infection.

Care must be taken when securing the luer connector and the suture clip to the catheter with ligatures to avoid cutting or crushing of the catheter tubing.

Patients undergoing external CSF drainage and/or ICP monitoring must be kept under continuous, close supervision for signs and symptoms of changing intracranial pressure due to excessive or insufficient drainage caused by improper drainage system adjustment or system failure. Excessive or insufficient drainage may result in potentially serious, life-threatening injury to the patient.

Correct alignment of the drainage system relative to the patient is critical for proper performance. Refer to the external CSF drainage and/or ICP system Instructions for Use for device specific alignment procedures.

Care must be taken in the routing and securing of the catheter tubing to the patient to ensure the catheter is not kinked, abraded, or unintentionally pulled from the patient.

Care must be taken when repositioning or moving the patient. Pressure level changes and patient repositioning should only be made by qualified personnel on the orders of a physician.

The physician must strongly consider removing the catheter if there are signs or symptoms of surgical site infection or meningeal irritation.

These products have not been tested for drug compatibility and therefore are not intended for drug administration.

Arkis BioSciences makes no claim for, or representation as to the performance characteristics of this product when it is used in conjunction with components of other manufacturers.

Complications
The principal complications associated with CSF drainage and ICP monitoring are catheter obstruction, surgical site infection, meningitis, ventriculitis, intracranial hypotension/hypertension, or hemorrhage. meningitis, ventriculitis, intracranial hypotension/hypertension, or hemorrhage may result in temporary or permanent brain damage.

Additionally, complications which may be associated with the use of the CerebroFlo™ EVD Catheter include the risks associated with the medications and methods utilized in the surgical procedure, as well as the patient's degree of intolerance to any foreign object implanted in the body.

The CerebroFlo™ EVD Catheter may be obstructed by particulate matter such as blood clots, fibrin, or brain tissue fragments. If not properly located in the lateral ventricle, the CerebroFlo™ EVD Catheter may become embedded in the ventricular wall or choroid plexus obstructing the catheter's drainage holes, resulting in insufficient drainage. Removal of an embedded catheter may cause bleeding. Less commonly, the CerebroFlo™ EVD Catheter may be obstructed by the reduction of the lateral ventricular size to slit-like proportions in patients with pre-existing small ventricles or in patients with excessive drainage.

How the CerebroFlo™ EVD Catheter is Supplied
The CerebroFlo™ EVD Catheter and package contents are supplied sterile and are non-pyrogenic, as noted on individual package labels. The CerebroFlo™ EVD Catheter and associated components are supplied in a sealed tray contained in sealed outer pouch. Do not use if package is damaged or open. Do not use if past the expiration date indicated on the individual package label.

Do Not Reuse or Resterilize
All CerebroFlo™ EVD Catheter kit components are single-use disposable devices. Do not reuse or resterilize any EVD Catheter kit components.

MRI Safety Information
The Trocar and Stylet provided to aid in the placement of the CerebroFlo™ EVD Catheter are MR-Unsafe.

The CerebroFlo™ EVD Catheter, Barbed Luer Connector, Male Luer Cap, and Suture Clip are MR-Safe.

Returned Goods Policy for the CerebroFlo™ EVD Catheter
Products must be returned in undamaged, unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless the products are returned due to a complaint of product defect or mislabeling.

Determination of a product defect or mislabeling will be made by Arkis BioSciences, which determination will be final.

Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

Product Ordering Information
Box of 5 CerebroFlo™ EVD Catheter Sets: Catalog Number 37.550.501

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

All products can be ordered through your Arkis BioSciences customer service representative.

Arkis BioSciences Inc.
P.O. Box 9815
1 Momentum Way
Knoxville, TN 37920
Telephone: 1-844-247-5383
Fax: 1-844-247-5383

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Symbols used in Labeling


Manufacturer


Expiration date

Catalog number

Batch code

Sterilized using ethylene oxide


Do not reuse


Do not use if package is damaged


Consult instructions for use

Rx ONLY
Caution: Federal law restricts this device to sale by or on the order of a physician.

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