Codman®

CODMAN® BACTISEAL® EVD Catheter Set

CODMAN® BACTISEAL® Clear EVD Catheter Set

Integra LifeSciences Production Corporation
11 Cabot Boulevard
Mansfield, MA 02048 USA

EC REP

Integra LifeSciences Services (France)
Immeuble Séquoïa 2
97 Allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest – France

CE
2797

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IMPORTANT INFORMATION
Please Read Before Use

CODMAN® BACTISEAL® EVD Catheter Set

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Rx ONLY

Indications
The CODMAN® BACTISEAL® EVD Catheter and CODMAN® BACTISEAL® Clear EVD Catheter Sets (BACTISEAL EVD Catheters), are indicated for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

Description
The BACTISEAL EVD Catheters are made of silicone tubing and are supplied sterile. BACTISEAL EVD Catheters are subjected to a treatment process by which the silicone tubing is impregnated with rifampin and clindamycin hydrochloride.

The catheter supplied in the BACTISEAL EVD Catheter Set is made of radiopaque (barium sulfate impregnated) silicone. The catheter in the BACTISEAL Clear EVD Catheter Set is made of clear silicone with a barium sulfate impregnated stripe. Laboratory studies show BACTISEAL treated catheters reduce the colonization of gram positive bacteria on the tubing surface.

The quantities of rifampin and clindamycin hydrochloride used to impregnate the BACTISEAL EVD Catheter are only a fraction of a therapeutic dose of these two antibiotics, and have no potential for any systemic therapeutic effect.

Each of the BACTISEAL EVD Catheters is a 35 cm silicone catheter. The catheter is marked with numbers or rings at each centimeter between 3 cm and 15 cm from the proximal tip. These markings serve as a scale to determine depth of insertion. The catheter characteristics vary by catalog number (see Table 1).

The product also contains the following items:

- A 36-cm straight stainless steel stylet used for catheter placement.
- A curved stainless steel trocar with a barbed end used for drawing the catheter subcutaneously.
- A female LUER-LOK® connector and LUER-LOK connector cap.
- A catheter anchoring clip.

Contraindications

Do not implant this device in patients with active infections, such as ventriculitis meningitis, or skin infections at or near the implantation site. Treat the infection before implanting this device.

Do not implant this device in patients with known hypersensitivity to rifampin or clindamycin hydrochloride.

Use of this device is contraindicated in patients receiving anticoagulants or known to have a bleeding diasthesis.

Adverse Effects

Particulate matter such as blood clots, brain fragments, or other tissue particles may obstruct the BACTISEAL EVD Catheter. In addition, the BACTISEAL EVD Catheter may become obstructed by excessive reduction of ventricle size.

The BACTISEAL EVD Catheter may be withdrawn from, or lost in, the lateral ventricles of the brain if it becomes detached from a securing scalp suture and/or an external CSF drain.

If not properly located in a lateral ventricle, the BACTISEAL EVD Catheter may be imbedded in the ventricular wall or choroid plexus.

Excessive CSF drainage may cause subdural hematomas, slit-like ventricles, and in infants, sunken fontanelles.

WARNINGS

Fibrous adhesions may bind the BACTISEAL EVD Catheter to the adjacent choroid plexus or the ventricular wall. Gentle rotation may free the catheter. DO NOT REMOVE THE CATHETER FORCEFULLY. If the BACTISEAL EVD Catheter cannot be removed without force, it is recommended to allow it to remain in place, rather than risk intraventricular hemorrhage.

Precautions

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged,
- contents appear damaged, or
- the expiry date has passed.

This device is for **single use only. Do not reuse.**

Use aseptic technique in all phases of the surgical procedure.

Do not immerse the BACTISEAL EVD Catheter in antibiotic solutions. Only use sterile water or normal saline to immerse the BACTISEAL EVD catheter as other solutions are not recommended and may cause precipitation and consequent adverse effects (e.g., catheter occlusion, hydrocephalus). Keep the time the BACTISEAL EVD catheter is immersed in sterile water or normal saline to a minimum (i.e., seconds) to reduce the risk of introducing infectious agents. A pale orange color may be imparted to the immersion solution.

Do not use sharp instruments when handling this product. Use shod forceps.

Take extreme care to prevent the catheter from coming in contact with towels, drapes, talc, or any linty or granular surfaces. Silicone rubber is highly electrostatic and, therefore, attracts airborne particles and surface contaminants that could produce tissue reaction.

Verify proper placement and integrity of all tubing junctions to prevent both obstruction of the BACTISEAL EVD Catheter lumen and tears or abrasions of the silicone tubing.

It is recommended that the catheter be sutured to the barbed end of the female LUER-LOK connector to prevent possible separation of the components when the catheter is removed.

Silicone cuts and tears easily. Care should be taken when placing ligatures so as not to tie them too tightly. The use of stainless steel ligatures on silicone rubber is not recommended.

To reduce the likelihood of infection, it is recommended that care of the catheter exit site and the connection to the external drain be carried out in accordance with principles established for the care of long-term hyperalimentation catheters.

Take care when removing and replacing the LUER-LOK cap to prevent contamination. To prevent contamination, do not touch the inside threads or surface of the LUER-LOK cap with bare fingers. Do not set the LUER-LOK cap on a non-sterile surface.

Refer to other manufacturer's instructions when using components other than Integra LifeSciences'.

Sterility

This product is for SINGLE USE ONLY; DO NOT RESTERILIZE. Integra Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminates such as Creutzfeldt-Jakob Disease. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

Integra LifeSciences Corporation will not be responsible for product that is resterilized, nor accept for credit or exchange product that has been opened but not used.

As long as the inner unit is not opened or damaged, the product is sterile.

The following components have been tested and were determined to be nonpyrogenic:

- catheter
- female LUER-LOK connector with LUER-LOK cap
- catheter anchoring clip

Storage

Store this product between 2°C (36°F) and 27°C (81°F), away from direct light. Do not remove the product from the packaging until it will be used.

Instructions for Use

Since the sites of insertion of the BACTISEAL EVD Catheter vary, decisions regarding the technique of insertion and verification of proper placement must be made by the surgeon on a case-by-case basis.

1. The operative site should be aseptically prepared and draped.
2. Perform the catheterization with the stylet in place in the BACTISEAL EVD Catheter; remove the stylet, check for free-flow of fluid. **Note:** When positioning the catheter, ensure that the tip of the stylet is fully seated in the tip of the catheter.
3. Attach the distal end of the BACTISEAL EVD Catheter to the barbed end of the trocar. Insert the sharp end of the trocar into the incision used for catheterization and tunnel subcutaneously for a short distance.
4. Bring the trocar out through the scalp. Taking care not to dislodge the intraventricular portion of the BACTISEAL EVD Catheter, draw the BACTISEAL EVD Catheter through the subcutaneous tunnel until the loop of the catheter no longer protrudes from the incision. Occlude the catheter with shod forceps.
5. Suture the distal end of the BACTISEAL EVD Catheter to the barbed end of the female LUER-LOK connector. Do not remove the LUER-LOK cap until you are ready to attach the BACTISEAL EVD Catheter to monitoring equipment or fluid collection equipment.