CODMAN NEURO

DePuy Synthes

BACTISEAL®
Endoscopic Ventricular Catheter
(REF 82-3087 & 82-3088)
IMPORTANT INFORMATION
Please Read Before Use

BACTISEAL® Endoscopic Ventricular Catheter
(REF 82-3087 & 82-3088)

Indications
The BACTISEAL Endoscopic Ventricular Catheter is designed for use in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain.

Description
The BACTISEAL Endoscopic Ventricular Catheter is designed to be placed with an endoscope, which functions as the stylet. The outside diameter of the endoscope must be 1.19 mm (0.047 inches) or less.

The endoscope will enable visualization of catheter placement. The tip of the catheter has been slit to allow passage of the endoscope through the catheter tip.

The BACTISEAL ventricular and peritoneal catheters are made of radiopaque (barium-impregnated) silicone tubing and are subjected to a treatment process by which the tubing is impregnated with rifampin and clindamycin hydrochloride.

BACTISEAL silicone catheters have been shown in laboratory studies to reduce the colonization of gram positive bacteria on the tubing surface.

The quantities of rifampin and clindamycin hydrochloride used to impregnate the catheters are only a small fraction of a therapeutic dose of these two antibiotics, and have no potential for any systemic therapeutic effect.
The ventricular catheter has an inner diameter of 1.4 mm and an outer diameter of 2.7 mm. The catheter is 14 cm in length and is supplied with 24 inlet holes (3 rows of 8 holes) at the proximal end. Depth marks have been added to the catheter (one dot at 5 cm and two dots at 10 cm). A right angle adapter is included.

A 120 cm peritoneal catheter is included only in catalog no. 82-3088. The peritoneal catheter has an inner diameter of 1.0 mm and an outer diameter of 2.2 mm. The catheter can be trimmed to length as needed.

**Contraindications**

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

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

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

**Adverse Events**

Particulate matter such as blood clots, brain fragments, or other tissue particles may obstruct the ventricular catheter; also, the ventricular catheter may become obstructed by excessive reduction of ventricular size to slit-like proportions.

The ventricular catheter may be withdrawn from, or lost in, the lateral ventricles of the brain if it becomes detached from the shunting system.

If not properly located in the lateral ventricle, the ventricular catheter may become embedded in the ventricular wall or choroid plexus.

Devices for shunting cerebrospinal fluid may have to be replaced at any time due to medical reasons or failure of the device.

Keep patients with implanted shunt systems under close observation for symptoms of shunt failure.
Complications of implanted shunt systems are mechanical failure, shunt pathway obstruction, infection, and cerebrospinal fluid leakage along the implanted shunt pathway.

Clinical signs and symptoms such as headache, irritability, vomiting, drowsiness, or mental deterioration may be indicators of a nonfunctioning shunt. Low-grade colonization, usually with Staph. epidermidis, may cause, after an interval from a few days to several years, recurrent fevers, anemia, splenomegaly, and eventually, shunt nephritis or pulmonary hypertension. An infected shunt system may show redness, tenderness, or an erosion along the shunt pathway.

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

**Magnetic Resonance Imaging (MRI) Information**

**MR**

The BACTISEAL Endoscopic Ventricular Catheter (catalog no. 82-3087) and the BACTISEAL Endoscopic Ventricular Catheter and Distal Catheter Kit (catalog no. 82-3088) have minor amounts of material that are metallic or conducting. These minor amounts of metallic materials will not pose an additional hazard to a patient undergoing an MRI procedure.

The metallic material tantalum is used for depth marking purposes on the ventricular catheter only. The tantalum constitutes less than 1% of the total mass of the ventricular catheter and, therefore, can be considered “MR safe.”

The distal catheter, contained in catalog no. 82-3088 only, contains no materials that are magnetic or conducting and, therefore, is “MR safe” in accordance with the American Society for Testing and Materials (ASTM) Standard F2503.

**WARNINGS**

Use the catheter only with components compatible with the dimensions shown in Description.
Fibrous adhesions may bind the catheter to the adjacent choroid plexus or the ventricular wall. Gentle rotation may free the catheter. DO NOT REMOVE THE CATHETER FORCEFULLY. If the catheter cannot be removed without force, it is recommended to allow it to remain in place, rather than risk intraventricular hemorrhage.

Precautions
Do not use the catheter or the endoscope if any damage is visible.

All procedures using an endoscope to place the slit ventricular catheter should be performed by a qualified neurosurgeon with neuroendoscopic experience.

Use aseptic technique in all phases of handling this product.

Do not immerse the BACTISEAL catheter in antibiotic solutions. When immersing the catheter in sterile water or saline, keep the time the catheter is immersed to a minimum. A pale orange color might be imparted to the immersion solution.

Use only with components compatible with the dimensions shown in Description.

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

Exercise 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, as a result, attracts airborne particles and surface contaminants that could produce tissue reaction.

Silicone has a low cut and tear resistance; therefore, exercise care when placing ligatures so as not to tie them too tightly. The use of stainless steel ligatures on silicone rubber is not recommended.

Exercise extreme care to prevent the ventricular catheter from coming in contact with towels, drapes, talc, gauze, or any linty or granular surfaces. Silicone rubber is highly electrostatic and, as a result, attracts airborne particles and surface contaminants that could produce tissue reaction.
Verify proper placement and integrity of all tubing junctions to prevent obstruction of the catheter lumen and tears or abrasions of the silicone tubing.

How Supplied

2

This product is for **SINGLE USE ONLY; DO NOT RESTERILIZE.** Codman & Shurtleff 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. Reuse can potentially compromise device performance and patient safety.

Codman & Shurtleff will not be responsible for any product that is resterilized, nor will we accept for credit or exchange any product that has been opened but not used.

As long as the individual package is not opened or damaged, the product is sterile and nonpyrogenic.

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. **The shelf life if this product is one year from the date of sterilization. The “Use By” date is indicated on the labeling.**

Instructions For Use

Since the sites of insertion of the ventricular 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.

**WARNING:** High intensity light from endoscopes may result in raising the tissue temperature near the tip of the endoscope. Do not allow the tip to contact or remain very close to tissue for a prolonged period of time.

1. Aseptically prepare and drape the operative site.
2. Prepare the catheter as follows:
   a. Remove the catheter from the package.
b. Gently roll the ventricular end of the catheter between your thumb and index finger to “pop” the slit in the tip open.
c. Hold the catheter by the open distal end with the proximal end pointing down.
d. Using a syringe with sterile water or saline, flush the ventricular catheter.
e. Insert the endoscope into the catheter and push the endoscope through the slit end of the catheter.
f. Retract the endoscope until it no longer protrudes beyond the slit.

3. With the endoscope functioning as a stylet within the catheter, perform the catheterization.

**WARNING:** Grasp the catheter and endoscope together so as to prevent inadvertent advancement of the endoscope beyond the catheter tip.

4. Once the catheter is within the ventricle, gently advance the endoscope while viewing its progress on the monitor. Carefully advance the endoscope 1 mm to 4 mm beyond the catheter to visualize catheter placement.

5. Make adjustments in the catheter position by moving the catheter and endoscope together to achieve optimum placement.

6. Maintain the position of the catheter using shod forceps. Withdraw the endoscope.

7. Check for free flow of cerebrospinal fluid and proceed with the remainder of the shunt procedure.

**Warranty**
Codman & Shurtleff, Inc. warrants that this medical device is free from defects in both materials and workmanship. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.** Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer’s instructions for use. There are no warranties that extend beyond the description on the face hereof.

® BACTISEAL is a registered trademark of Codman & Shurtleff, Inc.
Do not resterilize

Do not use if package is damaged

Rx Only Prescription device only (USA)

Manufacturer

Made in

Nonpyrogenic

MR MR Safe

Quantity

Sterilized using steam

Do not reuse

Caution

Consult instructions for use

*For recognized manufacturer, refer to product label.

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