

 **CODMAN 3000[®]**
Implantable Constant-Flow Infusion Pump



Codman
a Johnson & Johnson company

Your doctor has prescribed the CODMAN 3000 Implantable Pump for you because your treatment plan requires administration of continuous medication directly into a specific body site.

Your therapy requires the administration of

MEDICATION

to the

BODY SITE

Your CODMAN 3000 pump holds _____ ml's when filled.

Model 3000-16 (16 mL)

Model 3000 (30mL)

Model 3000-50 (50mL)

The information contained within this booklet will help you understand how the CODMAN 3000 Pump will be used in your treatment.

Codman & Shurtleff gratefully acknowledges the assistance of Linda Vanni, RN, MSN, CS, Clinical Nurse Specialist, Karmanos Cancer Institute, Detroit, Michigan, in the development and preparation of this important patient educational booklet.

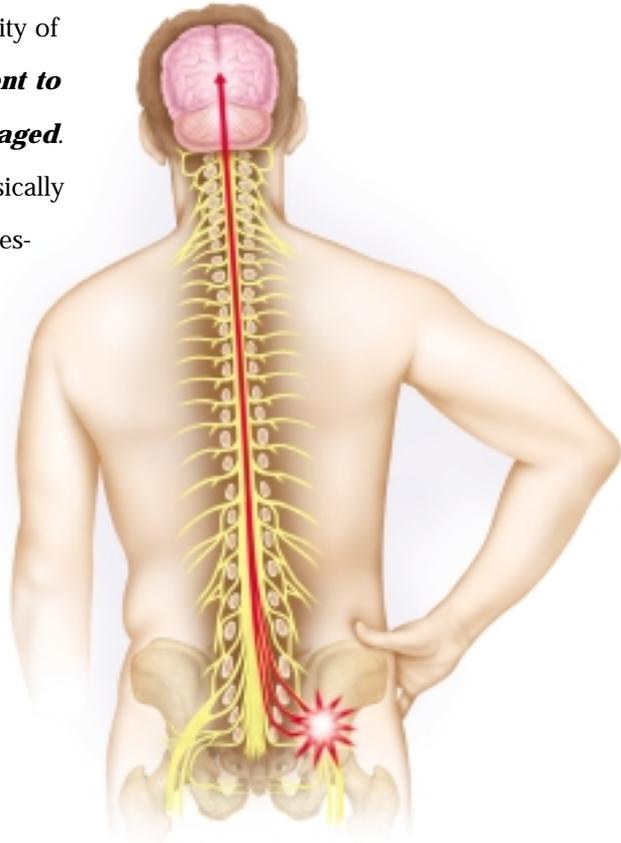
*Advances in pain management therapy have made it possible to produce technology that is both convenient and effective. Your healthcare team would like to provide you with this booklet, which contains important information regarding the **CODMAN 3000 Constant-Flow Implantable Pump**. In addition to outlining how the **CODMAN 3000 Constant-Flow Implantable Pump System** may benefit you, this booklet contains information that will help you make an informed decision regarding your pain management therapy.*

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■ *What is pain?*

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage.”¹ Pain is something that we all experience sometime in our lives. Pain is a very personal event and it has a different meaning to each one of us, involving both physical and emotional elements. It cannot be measured by any medical test; only the person experiencing pain can describe it. One of the ways in which pain is described is through the use of a ***pain scale***. Your healthcare provider will ask you to rate your pain on such a scale. This rating, provided only by you, will help to determine what pain management adjustments are necessary to keep your pain under control. You are the best judge of the type and intensity of your pain, and ***it is your right as a patient to have your pain assessed and managed.*** Uncontrolled pain is emotionally and physically draining and depletes the body of energy necessary for you to participate fully in your daily living activities. For these reasons, frequent communication with your healthcare team regarding your pain level is essential for optimum pain relief results.



■ *What are the types of pain?*

The pain that we usually experience is **acute** (short duration) and normally is relieved by oral medication. However, **chronic** pain is characterized by pain that is of a long duration (generally longer than 6 months). There are two types of chronic pain: **non-malignant** pain that may result from an injury or disease and **malignant** pain, also known as cancer pain, that is caused by a tumor or may be the result of cancer treatments.

Chronic non-malignant and cancer pain may require long-term pain management therapy to help the person achieve a satisfactory quality of life. Interventional therapies, like the pump, are offered when all other methods of pain control have produced unsatisfactory results.

■ *How is pain transmitted?*

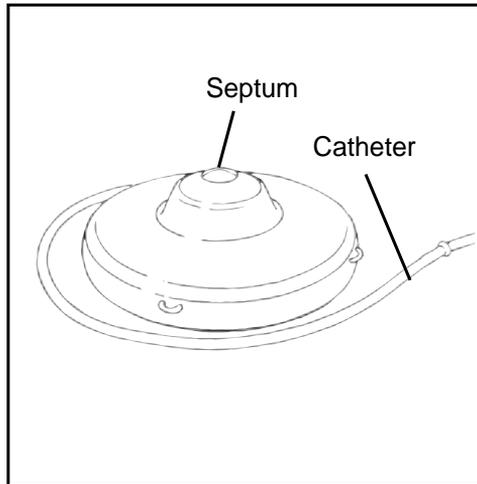
Years of research have helped the medical profession understand the basic mechanisms of how pain is transmitted.

All pain impulses are sent from the spinal cord to the brain where the pain impulses are recognized. No matter where the pain occurs in the body, the spinal cord receives the message. If the transmission of the pain is blocked at the spinal cord level before it reaches the brain, pain is felt to a lesser degree or not at all.

Blocking the pain impulse at the spinal cord level, before it reaches the brain, is the approach utilized with the CODMAN 3000 Pump.

■ *What is the CODMAN 3000 Pump?*

The CODMAN 3000 Pump is a small drug delivery system which is completely implanted beneath the skin. Depending upon the model selected by your doctor, the pump is about two to three inches in diameter, 3/4 to one inch thick, weighing four to six ounces, and approximately the size of a hockey puck.



The titanium pump is circular in shape with a small, raised area in the center

called a septum. This septum is where the health care provider uses a special needle to fill the pump's storage reservoir with pain medication via a needle stick through the skin. The medication flows from the drug chamber into the selected body site at a **constant rate** through a small flexible tube called a catheter. When using the CODMAN 3000 Pump, your surgeon places the catheter in the fluid surrounding the spinal cord.

Since the medication within the pump is being delivered directly to the spinal area, only a small amount of pain medication is required. The amount of medication your body needs to control your pain differs when it is delivered directly to the spinal area versus when it is consumed orally. This is because spinal delivery is targeted to the exact area where pain impulses are received; therefore a much smaller dose is required. The CODMAN 3000 Pump has been designed to hold approximately one ounce of medication. Frequently, use of the CODMAN 3000 Constant Flow Implantable Pump results in **effective pain relief and reduced side effects**^{2,3,4}.

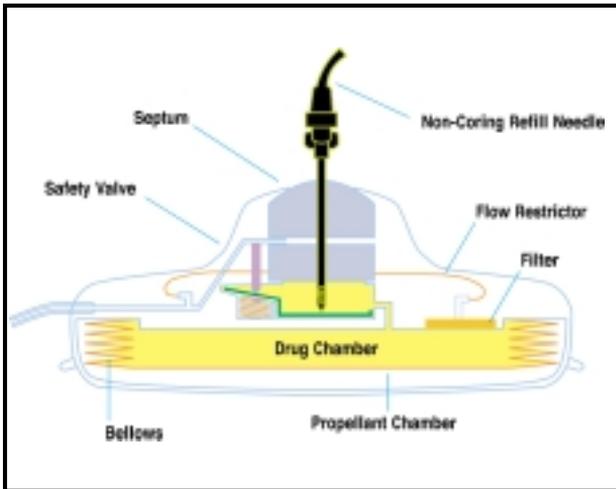
² Lamer TJ. Treatment of cancer-related pain: when orally administered medications fail. *Mayo Clin Proc.* 1994;69:473-480

³ Portenoy RK. Management of common opioid side effects during long-term therapy of cancer pain. *Ann Acad Med.* 1194;23:160-170.

⁴ Dougherty PM, Staats PS. Intrathecal drug therapy for chronic pain: from basic science to clinical practice. *Anesthesiology.* 1999;91:1891-1918

HOW DOES THE CODMAN 3000 PUMP WORK?

■ *How does the CODMAN 3000 Pump work?*



The CODMAN 3000 Pump is powered by a special process using two chambers to enable pain medication to flow at a constant rate without the use of a battery. Since no batteries are used, the CODMAN 3000 Pump is warranted for life and will not require replacement due to battery depletion.

The inside of the CODMAN 3000 Pump is divided into an inner chamber and an outer chamber by accordion-like bellows. The inner chamber, also known as the drug chamber, contains the pain medication to be delivered. The outer chamber contains a propellant that is permanently sealed inside.

The temperature of your body warms the propellant, which in turn causes constant pressure on the drug chamber and bellows. This pressure causes the medication to flow out of the drug chamber, through a filter and a flow restrictor, and then slowly out of the catheter. The flow restrictor ensures that the medication flows at the optimal, predetermined rate that your doctor has chosen.

Each time the pump is refilled, the propellant energy is recycled for another infusion period. Refilling the pump with medication expands the bellows and starts the pump on the next cycle of drug infusion. The pump may be refilled as many times as necessary for your therapy.

■ *Am I a candidate for the CODMAN 3000 Pump?*



Patients experiencing unrelieved **chronic pain** who have already tried oral or other pain management procedures may find implanted pump therapy beneficial. Many patients who receive oral or intravenous (IV) pain medications experience severe side effects such as nausea, vomiting, cloudiness, mental foginess, and constipation. Fortunately though, these same patients often find much fewer side effects with pain medications administered via the implanted pump.

■ *What is a trial?*

Before deciding if you are a candidate for a pump implantation, your doctor will most likely perform a “screening trial.” A trial can be performed in one of two ways. One method is a “single test dose.” This method is administered by an injection of the same drug that your doctor is considering for use in the pump. Utilizing this method, your doctor will inject a dose of medication directly into the area where the pump catheter will be placed. Results of this trial may be determined in less than twenty-four hours. Although this method is timely, it is also more difficult to evaluate true outcomes since performing the activities that normally make your pain worse will be difficult to do in the time allotted.

The second and more common method is the “functional trial.” During this method, your doctor will insert a tiny catheter (tube) into your back and attach it to an external drug pump. This procedure is often done using an x-ray machine. The external pump will then stay with you for several days. This method allows you to “test drive” the therapy before having a pump implanted. The goal is to mimic the pain relief that will be attained with an actual implanted pump. With a functional trial, you will be encouraged to perform your daily activities along with some possible limitations imposed by your physician. It is important that you perform your normal activities throughout each day so that you can see if this method of therapy will control your pain. Upon conclusion of the trial, your physician will remove the catheter and then discuss the results of the trial with you.

In conclusion of either screening trial method, you and your doctor will determine whether an implantable pump is right for your pain management therapy.

■ *How is the CODMAN 3000 Pump implanted?*

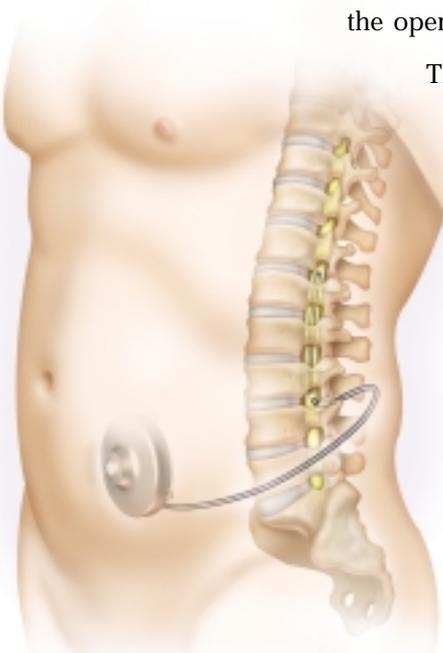
The implantation of the CODMAN 3000 Pump is done in the operating room under local or general anesthesia.

The surgery normally takes between one and three hours. Your surgeon will place the CODMAN 3000 Pump under your skin in your lower abdomen.

Prior to the surgery, your doctor or healthcare team member will ask if you have a preference as to which side the pump is placed. You may want to consider your side sleeping preferences so as to avoid placement of the pump pocket in an uncomfortable

location. You also may want to share with your doctor the types of clothing you normally wear. (E.g. If you normally wear pants with high waistbands or large belt buckles, you may want to place your pump a bit lower in the abdomen.) Your surgeon will make every attempt to place the pump on the side and location that you have selected.

On the day of your implant, you will be positioned on the operating room table lying on your side with the pump placement area facing up. Your surgeon will implant the pump in your abdomen and then extend a catheter that will go from the pump around your body (under your skin) into the spinal area. Once the catheter position is secured, your surgeon will place a bandage over the incision site where the catheter was inserted



on your back and over the incision site where your pump is located.

Although the pump is filled and begins to work immediately during surgery, some adjustments may be necessary over the next several weeks to obtain optimum pain relief. Your length of stay in the hospital depends on several factors but the most common hospital stay is 24 hours or less.

It is common to experience some soreness at the incision sites for the first few days after surgery. Also, you may experience some soreness along the tunneled site. This is the area going around your body from the pump incision site to the incision site on your back. After the incisions heal, no special care of the sites will be required and you will be able to shower and bath as usual.

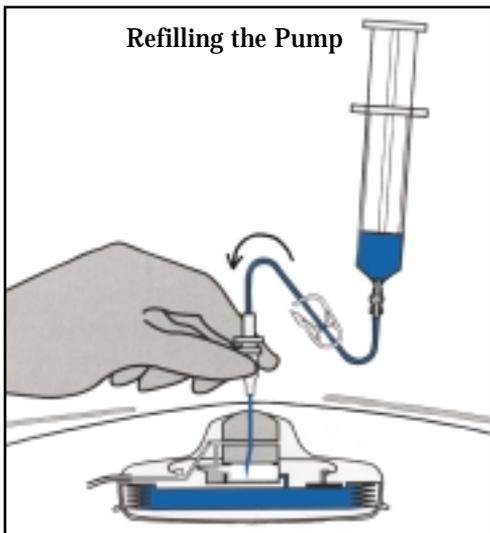
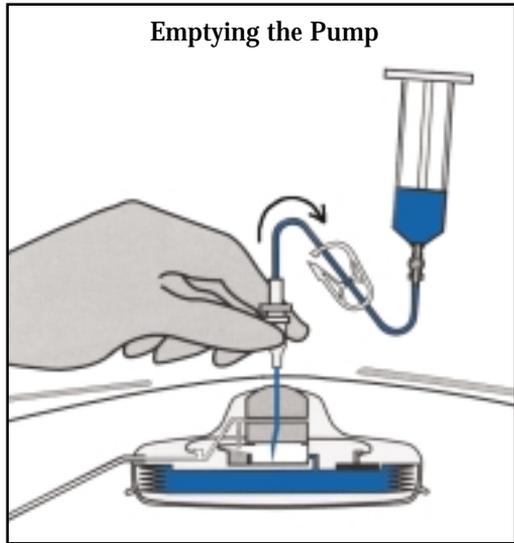
Prior to your discharge, your doctor or health care team member will provide you with important information regarding your new CODMAN 3000 Pump and instructions for the care of the incisions. You will also receive a **Codman Patient Medical Alert Card** for identification. You should carry this card with you at all times.



■ *How is the CODMAN 3000 Pump refilled?*

Depending upon the flow rate of your individual pump, your doctor or nurse will refill the pump every four to eight weeks. When you go into the office for a scheduled visit, a member of the health-care team will begin by cleaning your skin at the pump site. A special needle with a syringe attached will then be inserted into the septum in the top of the pump. You will feel a mild “pinprick” sensation as the needle passes through

the skin into the septum. This will allow all the medication remaining in the pump to flow out of the pump into the syringe. Next, a syringe containing the refill pain medication will be attached to the needle already in place, and the pump will be



refilled. Refilling the pump with medication expands the bellows and starts the pump on the next cycle of drug infusion. The refill procedure takes approximately 10-15 minutes.

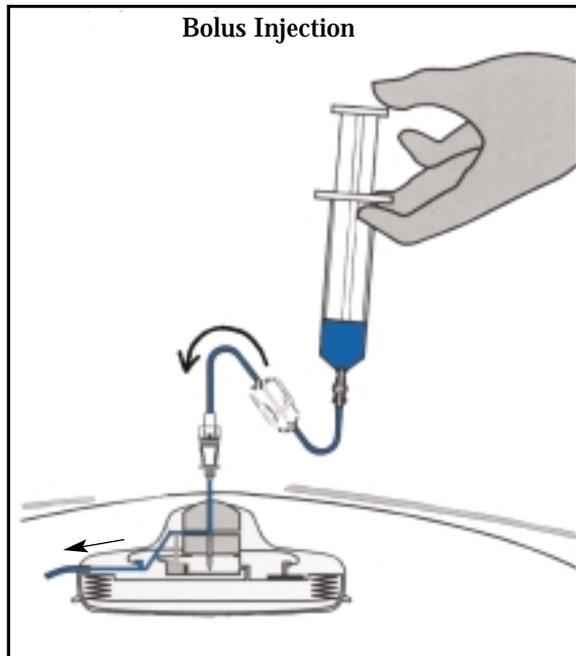
HOW IS A BOLUS INJECTION PERFORMED?

■ *How is a bolus injection performed?*

In addition to the continuous infusion capabilities of the CODMAN 3000 Pump, medication can be delivered to the tip of the catheter via the bolus pathway injection.

There may be times when your doctor may want to flush the catheter or give you an injection of medication directly into your body through the catheter. This is done through the septum of your pump using a CODMAN 3000 Bolus Needle. This needle is designed with a special opening which, when inserted into the septum, allows the drug or fluids to be injected directly into the catheter.

This procedure can be done for several reasons, including a dye study. A dye study allows the doctor to check the catheter for correct placement and is performed in the x-ray department. Your doctor or nurse will explain additional uses for the bolus injection pathway. As in the pump refill procedure, you should only feel a mild “pinprick” sensation as your pump is accessed.



■ *Will people notice the pump?*



You will notice a slight bulge at the location where the system is implanted. But under loose-fitting clothing, it can't be noticed. Remember, at first the pump at your side may take some time to get used to. However, many patients tell us that shortly after the implant they don't even realize it is there.

■ *What are my responsibilities as a patient?*

Successful pain management involves a partnership between you and your healthcare providers. This partnership involves responsibilities for both parties. Your healthcare provider's responsibilities include keeping you as comfortable as possible with minimal side effects and responding to your pain management needs in a timely manner. ***Your responsibilities as a patient include setting realistic goals for your pain management, maintaining open communication with your healthcare providers, and keeping your scheduled pump refill appointments.***

■ *Patient Testimonials*

In their own words, patients implanted with the CODMAN 3000 share their experiences:

Ron, Pump Recipient

Post-Implant

"Before the pump I couldn't think clearly because of all the medication I was taking.

Now, I think clearly and I can remember things.

I recently went on a trip to Alaska and traveled all around in an RV.

I never would have made this trip if I didn't have the pump."

Lizanne, Pump Recipient

Pre-Implant

"I felt disoriented. I didn't remember things."

Post-Implant

"I'm not foggy. I can see what's going on around me. I'm not cranky all the time and I'm not depressed all the time. The pump has really given me my life back."

"My image of myself is fine with the pump. People don't know that it's there.

*If I didn't actually tell somebody
and show them where it is, they wouldn't know it."*

Michele, Pump Recipient

Post-Implant

"It's pretty maintenance free.

The only thing you have to do is go in for a refill."

■ *Frequently Asked Questions*

Q. **Do I have to limit my activities?**

Once you have recovered from surgery, you will be able to continue most of the activities you enjoyed before the surgery. Your doctor or nurse will be able to give you guidelines, however there are a few specific things to remember:

- Avoid rough physical activity like contact sports to protect the pump site.
- Avoid deep sea and scuba diving. Increased pressures will affect the flow rate of the pump. Snorkeling and swimming will have no effect on the flow rate, so you may continue these activities.
- Do not place heating pads and/or water bottles directly over the pump implant site. Direct contact of the heating pad or water bottle over the pump pocket site will increase the local temperature, thereby causing the pump to flow slightly faster.
- Minimize your exposure to saunas and hot tubs for extended periods of time. Prolonged exposure will elevate your body temperature and may cause your pump to flow faster.
- Let your doctor know if you plan to travel by air or move to another location as your pain medication may need to be adjusted.
- Call your doctor or nurse if you have a fever, if there is any change at your pump site, or if your pain management is ineffective.

Q. **Will my insurance company pay for the CODMAN 3000 Pump?**

Insurance coverage differs from company to company. However, most insurance companies will provide financial support for the placement and care of the pump. To be sure, check with your insurance carrier to determine the extent of your coverage.

Q. **What happens if I miss a scheduled appointment?**

It is very important for you to keep your refill appointments so that the pump does not run dry. If you cannot keep an appointment, be sure to call your doctor or nurse for alternate arrangements.

Q. Can I travel with my CODMAN 3000 Pump?

Your CODMAN 3000 Pump should not stop you from enjoying travel. It is your responsibility to let your doctor know before you travel if you plan to be away for longer than your scheduled refill period. Your doctor can refer you to a physician in another area while you are on vacation. Although unlikely, it is possible that the airport security system will detect your pump. If this does occur, simply present your Codman Patient Identification Card to the security personnel.

Q. Can I safely have an MRI procedure with the pump?

Yes. The pump is made of surgical grade titanium which does not affect an MRI and has had extensive testing done by Codman to confirm this.

Q. I'm concerned about addiction. Do I have reason to worry?

Addiction is uncommon in patients who take pain medication for pain. The following definitions will help you understand the different terms.

- **Addiction** is the psychological dependence on a drug and involves compulsive abnormal behavior to obtain the drug for non-medical purposes. Addiction causes a person to take more drugs than is needed with little or no decrease in their pain.
- **Tolerance** is the process in which increased amounts of pain medication is needed in order to achieve the same amount of pain control.
- **Physical dependence** is a physical state of reliance on pain medication as exhibited by withdrawal symptoms when the drug is withheld.
- **Withdrawal** occurs when pain medications are abruptly stopped or reversed and symptoms emerge. Common symptoms associated with withdrawal include abdominal pain, nausea, vomiting, diarrhea, sweating, agitation, anxiety, and sleeplessness.

Q. Will I need to have the CODMAN 3000 Pump forever?

The majority of patients do continue their pump therapy indefinitely. If the cause of the patient's pain is eliminated, the pump can be surgically removed while the patient is weaned off of pain medications.

■ *If you should have concerns or questions:*

Your doctor or nurse will help you and your family understand how the CODMAN 3000 Pump works. If you should feel uncomfortable or have any questions, you should contact the individuals listed below for assistance.

Physician

Phone

Nurse

Phone

Your first refill appointment is scheduled for:

Date/Time

Clinic/Physician's Office

Phone

LIMITED LIFETIME WARRANTY

CODMAN Model 3000 Series Implantable Pumps

Codman & Shurtleff, Inc., 325 Paramount Drive, Raynham, Massachusetts hereby warrants solely and exclusively to the first authorized patient user (“User”) who receives a CODMAN 3000 Constant Flow Implantable Pump (“Pump”), during the LIFE of such User of the Pump, that Codman will provide such User with a functionally comparable replacement Pump at no charge if the original Pump fails to function properly, due to defects in either workmanship or materials, but such replacement shall be provided only if the following four conditions are satisfied:

1. The Pump must be used consistent with the instructions set forth in the Instructions for Use Manual provided by Codman with each Pump.
2. Device Registration Records must be filled out and returned to Codman within thirty (30) days of Pump implantation.
3. The Pump which fails to function properly must be returned to Codman within thirty (30) days of its explantation. Upon return of the Pump to Codman it shall become the sole property of Codman.
4. The User of the Pump must agree to take all necessary steps to provide Codman with full access to all patient, hospital, physician and related medical records which might be relevant to this Limited Warranty.

This Limited Warranty applies only to the use of the Pump by the User and the liability of Codman is limited solely and exclusively to the replacement of the Pump under the conditions set forth herein. Replacement of the Pump includes only an actual device and does not include the cost of any medical care. No person is authorized to bind Codman to any warranty of a Pump, except this Limited Warranty.

This Limited Warranty does not apply to occlusion or shearing of the catheter portion of the Pump which results in the explantation of Pump, nor to any accessory products.

No representation or warranties are made: (a) that failure of the Pump will not occur or (b) that a User will not react adversely to the implantation of the Pump or (c) that medication used in conjunction with the Pump will be safe and effective for the treatment of the User's condition. Codman disclaims all responsibility for medical complications, including death, which may result from the use of the Pump.

NO WARRANTY IS MADE BY CODMAN, EXCEPT AS EXPRESSLY HEREIN PROVIDED, AND CODMAN FURTHER EXCLUDES AND DISCLAIMS, TO THE EXTENT PERMITTED BY ALL APPLICABLE LAW, ANY AND ALL EXPRESS AND IMPLIED WARRANTIES IN CONNECTION WITH THE DESIGN, SALE, MERCHANTABILITY, USE OR FITNESS OF THE PRODUCTS FOR ANY PARTICULAR PURPOSE OR USE. CODMAN SHALL NOT HAVE ANY LIABILITY FOR INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, NOT WITHSTANDING WHETHER LIABILITY IS ASSERTED ON WARRANTY, CONTRACT, TORT OR OTHER CLAIMS, ANY AND ALL LIABILITY OF CODMAN SHALL BE LIMITED TO THE COST OF THE REPLACEMENT OF THE PUMP. THE LIMITED WARRANTY SET FORTH ABOVE IS THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON. IN THE EVENT THAT ANY PROVISIONS OF THIS LIMITED WARRANTY ARE HELD BY A COURT OF COMPETENT JURISDICTION TO BE ILLEGAL, UNENFORCEABLE OR IN CONFLICT WITH THE APPLICABLE LAW, THE REMAINING PROVISIONS HEREOF SHALL REMAIN IN EFFECT.

Who is Codman?

CODMAN, a Johnson & Johnson company, develops a wide range a diagnostic and therapeutic products for the treatment of central nervous system disorders. Our focus is on Intractable Pain Management, Pediatric & Adult Hydrocephalus, and Neuro Critical Care.

For more than 160 years, Codman has continued to pursue the same principles upon which it was founded: Quality, Innovation, and Excellence.

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