

PATIENT INFORMATION BOOKLET

 **CODMAN<sup>®</sup>3000**  
Implantable Constant-Flow Infusion Pump



**Now With a Limited  
Lifetime Warranty**



**Codman**  
a *Johnson & Johnson* company

*For more information, contact your Codman Drug Delivery Sales Representative*

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a *Johnson & Johnson* company

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

Your therapy requires the administration of

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MEDICATION

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to the

BODY SITE

Your CODMAN Model 3000 pump holds \_\_\_\_\_ mL's when filled.

Model 3000-16 (16 mL)

Model 3000 (30mL)

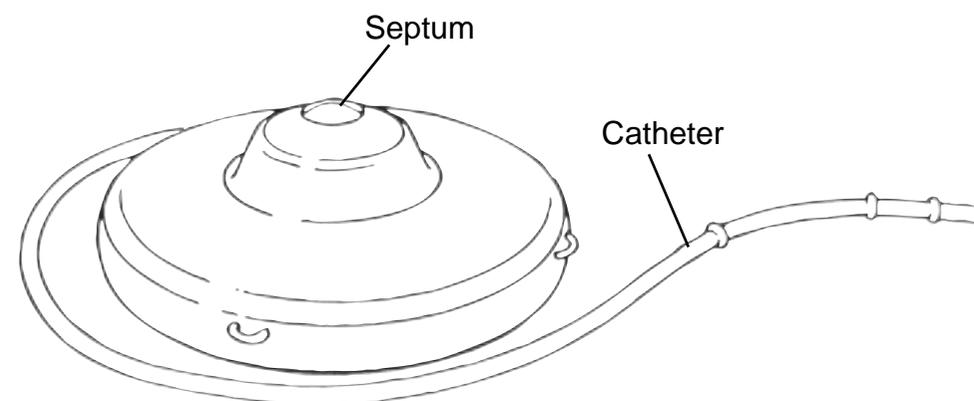
Model 3000-50 (50mL)

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

### *What is the CODMAN Model 3000 Pump?*

The CODMAN Model 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 approximately two to three inches in diameter, 3/4 to one inch thick and weighs four to six ounces. The titanium pump is circular in shape with a small, raised area in the center called a septum.

The septum is where the special non-coring refill needle is inserted when the pump is filled with medication. The medication flows from the drug chamber into the selected body site through a small flexible tube called a catheter. The pump holds one ounce of medication which is continuously released while you are going about your daily activities.



CODMAN Model 3000 Implantable Pump

### *How is the CODMAN Model 3000 Pump implanted?*

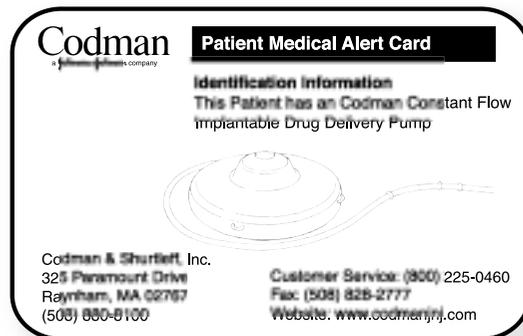
Your surgeon will place the CODMAN Model 3000 Pump under your skin in a pocket made between the skin and muscle in your lower abdomen or upper chest cavity. The catheter will be placed into a selected body site. The pump will be filled at the time of your operation and will begin working immediately.

The surgical procedure to implant the CODMAN Model 3000 Pump is usually performed under general anesthesia and normally takes one hour. If needed, any additional surgery may be performed at this time. If this is the case, your surgery may take longer than one hour.

Your stay in the hospital after the surgery will depend on the amount of surgery performed at the time of your pump implant.

You will usually have a bandage over the incision site. Your doctor or nurse will provide you with instructions for the care of the implant site. Once the incision has healed the site will no longer require any special care.

After your surgery, your doctor or nurse will give you an Identification Card that you should carry with you at all times.

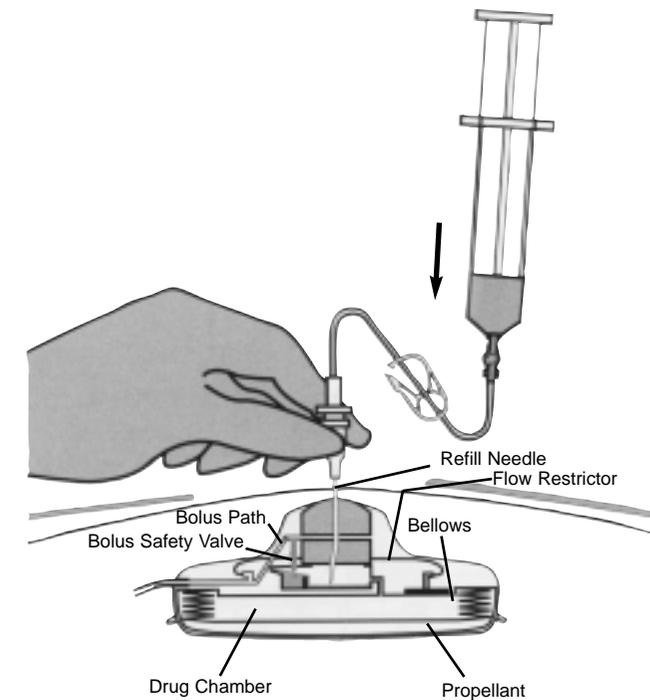


### *How does the CODMAN Model 3000 Pump work?*

The inside of the CODMAN Model 3000 Pump is divided into inner and outer chambers by an accordion-like bellows. The inner chamber contains the medication to be infused. The outer chamber contains a propellant permanently sealed inside. The temperature of your body warms the propellant.

The warmed propellant exerts a constant pressure on the bellows causing the medication to flow out of the inner chamber, through a filter and flow restrictor, and then slowly out the catheter.

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.



Refilling the Pump

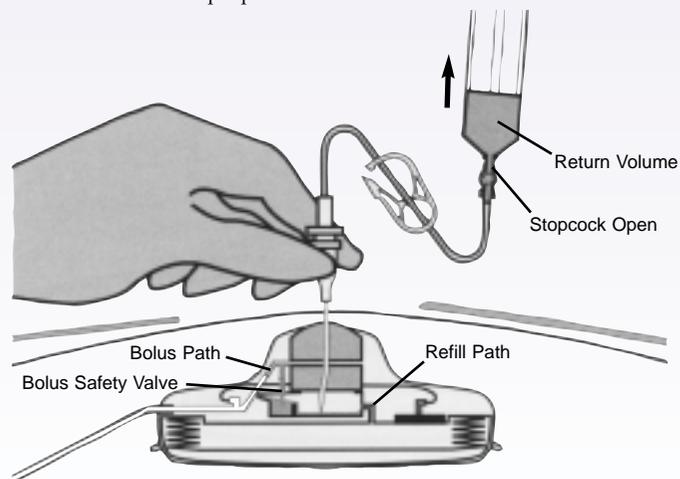
### Using the CODMAN Model 3000 Pump for treatments:

The CODMAN Model 3000 Pump can be used to deliver medication in two ways. One method is CONTINUOUS INFUSION and the other is BOLUS Injection.

#### CONTINUOUS INFUSION:

Continuous infusion is used from the time the CODMAN Model 3000 Pump is implanted in surgery. Depending upon the flow rate of your individual pump, your doctor or nurse will refill the pump every two to eight weeks.

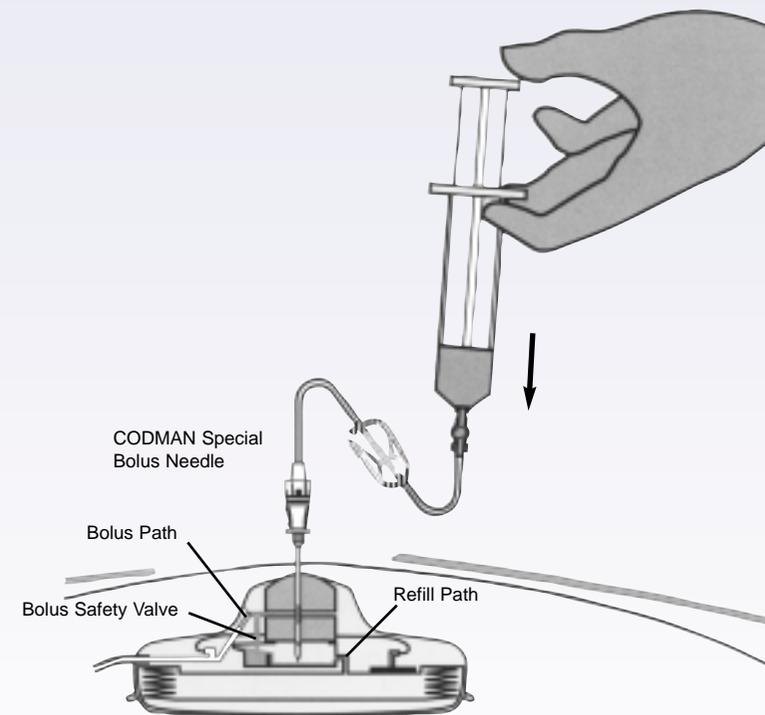
After cleaning your skin at the pump site, a special non-coring refill needle with a syringe attached will be inserted into the septum in the top of the pump. You will feel a mild “pinprick” sensation as the needle passes through the skin into the septum. This will allow all the medication which remains in the pump to flow out of the pump into the syringe. The amount of fluid removed will be measured so your doctor will be sure you receive the proper amount of medication. Next, a syringe containing the refill medication will be attached to the needle already in place and the pump will be refilled. The refill procedure takes 10-15 minutes and you should not feel pain other than the “pinprick” sensation.



Emptying the Pump

#### BOLUS 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 in the top of your pump using a CODMAN Model 3000 Special 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, which will be explained by your doctor or nurse. As in the pump refill procedure, you will only feel a “pinprick” as your pump is accessed.



Bolus Injection

### *Activities after the pump is implanted:*

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:

1. Avoid rough physical activity like contact sports which might cause a blow to the pump site.
2. 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.
3. 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 faster.
4. Avoid saunas, long periods in hot tubs, and prolonged direct sun exposure because your pump will flow faster if your body temperature is elevated.
5. Let your doctor know if you plan to travel by air or move to another location as your medication may need to be adjusted.
6. Call your doctor or nurse if you have a prolonged fever.

### *Common questions patients have about the CODMAN Model 3000 Pump:*

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

It is very important for you to keep your appointments because the pump may 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 Model 3000 Pump?**

Your CODMAN Model 3000 Pump should not stop you from enjoying travel. Let your doctor know 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.

#### **Q. Will the CODMAN Model 3000 Pump activate airport security systems?**

It is highly unlikely that the airport security systems will detect such a small amount of metal. If this does occur, present your Patient Identification Card to security.

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

Insurance coverage differs from company to company. Check with your insurance carrier to determine the extent of your coverage.

***If you should have concerns:***

Your doctor or nurse will help you and your family understand the medicine in the pump and how the pump works. If you should feel uncomfortable or have questions or concerns, you may contact the individuals listed below for assistance.

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 PHYSICIAN

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 PHONE

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 NURSE

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 PHONE

Your first refill appointment is scheduled for

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 DATE/TIME

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 CLINIC/PHYSICIAN'S OFFICE

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 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 Model 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 explanation. 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 explanation 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, NOTWITHSTANDING 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 IS 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.