

**Bristol-Myers Squibb Company**

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# Sharps Management Plan

**October 2011**

BMS Sharps management plan for the Continental United States, Alaska and Hawaii.

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## Introduction

As some States have approved regulation for the management of Household Generated Sharps Wastes during the past years, Bristol-Myers Squibb (BMS) has prepared the following Sharps Management Plan to support in the safe collection and proper disposal of waste sharps. Under various state sanctioned regulations, pharmaceutical manufacturers that sell or distribute a medication that is self administered at home through the use of hypodermic needles or other self-injectable devices have to prepare and submit to the State, or its responsible agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste sharps. These regulations require the manufacturer to post and maintain the plans on their respective Internet web sites. Currently two states have issued Sharps management regulations, California and Minnesota. For California, the plan must be submitted to the California Integrated Waste Management Board (Board) for posting, and posted on BMS web site. The State of Minnesota only requires that the plan is posted on Bristol-Myers Squibb web page.

Bristol-Myers Squibb has been conducting several clinical trials in various States, which involve subcutaneous injection of our pharmaceuticals. These clinical trials are administered at clinical investigative sites located throughout California, Minnesota and other states by third parties. In each of these trials, the patients are provided injectable sharps to self-administer the medication in a home environment and also puncture resistant containers for the safe collection of the used sharps. As an element of the clinical trial, patients are provided with

instructions on the proper administration of the medicine and requested to return the used sharps materials to these investigative sites using the puncture resistant containers. Disposal of these sharps is coordinated by the clinical investigational site using the third party disposal contractors.

As of October 2011, BMS initiated the commercial distribution of a medicinal product that will be self-injected at home. Under this BMS Sharps Management Plan, BMS will offer customers that utilize self-injectable sharps, instructions and/or recommendations on how to handle the used sharp and on how to properly dispose of these materials. In addition, customers may be chosen to participate in a program that offers an empty sharps container and return mail-back program, which allows for both the adequate disposal of needles and also patient convenience, at no cost to the customer. This sharps container mail-back program will be managed by a third party and fully funded by Bristol-Myers Squibb.

This Sharps Management Program and some related reference guidance will be available at the following Internet web sites:

[http://www.bms.com/ourcompany/compliance\\_ethics/Pages/default.aspx](http://www.bms.com/ourcompany/compliance_ethics/Pages/default.aspx)  
[http://www.bms.com/sustainability/social\\_progress/our\\_communities/Pages/product\\_responsibility.aspx](http://www.bms.com/sustainability/social_progress/our_communities/Pages/product_responsibility.aspx)

Additional Sharps disposal guidance for all states is available at the following web pages:

<http://www.safeneedledisposal.org/>  
<http://www.epa.gov/wastes/wyl/stateprograms.htm>  
<http://www.epa.gov/wastes/nonhaz/industrial/medical/disposal.htm>

## Elements of the BMS Plan

### Safe collection and proper disposal of the waste devices

Sharp waste generated by self administration of an injectable drug could occur throughout the United States. As an element of the clinical study, patients are requested to return their used sharps to the clinical investigative sites, using the provided puncture resistant containers. The investigative sites ultimately dispose of these sharps and containers, in accordance with applicable regulatory requirements. These home-generated sharps materials are not expected to enter into the pertinent municipality trash cycle.

For sharp waste generated by self-injectable drugs, administered at home, customers can choose to participate in an optional service that provides a free sharps container and mail-back program allowing for adequate sharps disposal and patient convenience. BMS has contracted the services of a third party service provider that will ensure the supply of the sharps container, will arrange for the proper shipment and disposal of the sharps, and will be fully funded by Bristol-Myers Squibb. Questions about the program can be answered through the BMS Customer Service line at 1-800-332-2056.

Additional collection and disposal information may be obtained at most pharmacies and at state environmental agency websites. The current guidance web pages for the States of California and Minnesota are listed in Appendix B. Guidance on other states' requirements can be located in the web pages listed in Appendix C.

## Educate consumers about safe management and collection opportunities

The patients enrolled in applicable BMS clinical trials involving self-injectables are provided with a puncture-resistant sharps container marked with the biohazard label for the safe collection of the used sharps. The patients are provided with written instructions on the proper use and disposal of the sharps container (see an example at Appendix A).

Patients receiving a commercially supplied, BMS self-injectable product will receive Patient Prescribing Information, which includes instructions on the proper handling of waste sharps. The pamphlet will instruct patients on the basic disposal requirements.

Additional education and supporting information on Waste Sharps management can be found in Appendix C

**Support efforts of groups with interest in protecting public health and safety through the safe collection and proper disposal of waste devices**

BMS continues to evaluate employing “safe needle technologies” (i.e. retractable needles; use of a blunting media) for our future products. Such technologies/approaches aim to further reduce the potential for inadvertent “sticks”.

Appendix A: Sharps Container User Requirements



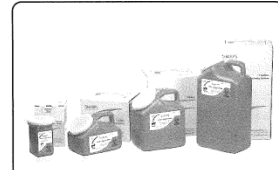
**Instructions for Use**

#10100, #11000, #11002, #11003,  
 #12000, #12002, #13000, #13002, #13004

**1 Quart, 1, 2, or 3-Gallon Sharps® Recovery System**

This Sharps Compliance, Inc. Sharps® Recovery System (System) contains everything required to safely package your needles, syringes, lancets and other biohazardous materials to be mailed for proper treatment.

Go to [www.sharpsinc.com](http://www.sharpsinc.com) for more information.



1 Quart, 1, 2, and 3-Gallon Sharps® Recovery Systems

**CONTENTS**

- Outer shipping box with pre-attached USPS Merchandise Return Label (return postage is prepaid)
- Inner box lined with 4 mil plastic bag
- 1 quart, 1, 2, or 3 gallon sharps collection container(s) with absorbent pad
- Tape, twist-tie, and instructions
- Tracking Document on outside of shipping box

**PRECAUTIONS – READ PRIOR TO PROCEEDING**

- DO NOT place mercury or lead-containing devices or batteries into this container.
- DO NOT place drugs or chemotherapeutic agents into this container. Contact Sharps at 800-772-5657 for the appropriate System or labeling method to assure proper treatment.
- Never try to retrieve anything from sharps collection containers(s).
- Always keep containers secured from unauthorized persons.
- Follow proper packaging instructions.
- Comply with all laws and regulations regarding handling, transport, and tracking of this product. Contact your state or Sharps at 800.772.5657 with questions. New Jersey regulated generators attach NJ Tracking Form to Sharps manifest tracking form before placing into the plastic pouch for mailing.
- DO NOT OVERFILL. (FILL LINE IS NOTED ON CONTAINER LABEL). LID MUST FIT DOWN TIGHTLY.
- DO NOT compress or force materials into the containers.
- Containers are puncture-resistant, not puncture-proof. Carry full containers by top or handle.
- DO NOT place more than 50ml (1.66 ounces) of liquids into container(s).
- DO NOT mail container(s) in any box other than the one supplied with this system.
- Refer to the chart below for maximum return weight for each system.



**Figure 1**  
Place sharps into container.



**Figure 2**  
Firmly snap lid over opening to close.

| Container Size: | 1 Quart System | 1 Gallon Systems |        | 2 Gallon Systems |        | 3 Gallon Systems |        |        |        |
|-----------------|----------------|------------------|--------|------------------|--------|------------------|--------|--------|--------|
| Model:          | 10100          | 11000            | 11002  | 11003            | 12000  | 12002            | 13000  | 13002  | 13004  |
| Max. Wt.        | 5 lbs          | 10 lbs           | 17 lbs | 25 lbs           | 17 lbs | 25 lbs           | 25 lbs | 25 lbs | 25 lbs |

**FOR ASSISTANCE OR TO ORDER REPLACEMENT COMPONENTS, CALL 800.772.5657**

**TRAINING & INSTRUCTIONS FOR YOUR SHARPS® RECOVERY SYSTEM**

- Order your new Sharps® Recovery System before this container is filled.**
1. Remove container(s) from packaging and place at point(s) of use. Save all components for repackaging System for mailing.
  2. Place sharps or biohazardous materials into container(s) (Fig.1).
  3. Close lid by snapping firmly over opening (Fig. 2). Make sure lid is tightly sealed prior to packaging for mailing.
  4. When ready for mailing, place container(s) into the plastic bag and box. Securely seal bag around container(s) using twist-tie.
  5. Close the box flaps and tape. Write facility return address on the top of the box.
  6. Remove the manifest tracking form from the plastic pouch located on the outside of the white shipping box. Fill out the top portion of the form completely and sign it. Remove the bottom copy of the form and retain it for your records. Return the remaining copies of the form into the plastic pouch with the barcode facing out. POST OFFICE WILL NOT ACCEPT YOUR BOX WITHOUT THE MANIFEST TRACKING FORM.
  7. For tracking purposes, log on to your SharpsTracer account at [www.sharpstracer.com](http://www.sharpstracer.com) and enter the box number. To sign up for this free service, call 800.772.5657.
  8. Take the properly sealed package to any U.S. Post Office, give to your postal carrier, or arrange a priority pickup from your post office at [www.sharpsinc.com](http://www.sharpsinc.com). DO NOT TRY AND SHIP THROUGH UPS or FedEx. Postage will be paid by Sharps Compliance.
  9. Download your Proof of Recovery from your SharpsTracer account at [www.sharpstracer.com](http://www.sharpstracer.com) in 30-45 days.

**IN CASE OF EMERGENCY OR DISCOVERY OF DAMAGE OR LEAKAGE, CALL 1.800.772.5657**

For more information regarding the intended use of the Sharps Collection Container, call 800.772.5657.



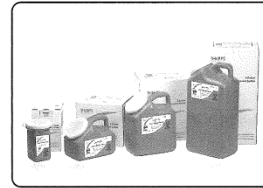
**Instrucciones de uso**

#10100, #11000, #11002, #11003,  
 #12000, #12002, #13000, #13002, #13004

**Sistema de recuperación de Sharps® (objetos punzantes) de 1 cuarto de galón, 1, 2, o 3 galones**

Este Sistema de Recuperación de Sharps® (objetos punzantes) de Sharps Compliance, Inc. contiene todo lo necesario para envasar en forma segura sus agujas, jeringas, lancetas y otros materiales de riesgo biológico para enviarlos para su tratamiento adecuado.

Diríjase a [www.sharpsinc.com](http://www.sharpsinc.com) para obtener más información.



Sistemas de recuperación de Sharps® de 1 cuarto de galón, 1, 2 y 3 galones.

**CONTENIDO**

- Caja exterior de embalaje con etiqueta autoadherida de Devolución de Mercadería del Correo de EE.UU. (USPS) (con franqueo de devolución prepago)
- Caja interna forrada con una bolsa de plástico de 4 mil. de grosor
- Envase(s) de recolección de objetos punzantes de 1 cuarto de galón, 1, 2 o 3 galones con almohadilla absorbente
- Cinta adhesiva, tirilla de amarre (twist-tie) e instrucciones
- Documento de seguimiento de guía de carga en el exterior de la caja de embalaje

**PRECAUCIONES – LEA ANTES DE PROCEDER**

- NO coloque dispositivos o baterías que contienen mercurio o plomo en este envase
- NO coloque drogas o agentes quimioterapéuticos en este envase. Contacte a Sharps al 800-772-5657 para informarse sobre el sistema o el método de etiquetado adecuado que asegure el tratamiento apropiado.
- Nunca Intente extraer algo del (de los) envase(s) de recolección de objetos punzantes.
- Mantenga siempre los envases fuera del alcance de las personas no autorizadas.
- Siga las Instrucciones apropiadas de embalaje.
- Cumpla con todas las leyes y reglamentaciones referentes al manejo, transporte y seguimiento de este producto.
- Contacte a sus autoridades estatales o a Sharps al 800.772.5657 si tiene preguntas. Los generadores de envío sujetos a reglamentaciones de New Jersey deberán adjuntar el Formulario de Seguimiento de NJ a la Guía de Carga de Sharps antes de colocarla en la bolsa de plástico para su envío.
- NO SOBRELLENE. (LA LÍNEA DE LLENADO ESTÁ MARCADA EN LA ETIQUETA DEL ENVASE). LA CUBIERTA DEBE AJUSTARSE FIRMEAMENTE.
- NO comprima ni fuerce los materiales en los envases.
- Los envases son resistentes a los pinchazos pero no son a prueba de pinchazos. Transporte los envases llenos sujetándolos por la parte superior o la manija.
- NO coloque más de 50ml (1.66 onzas) de líquidos en el (los) envase(s).
- NO envíe por correo el (los) envase(s) en una caja que no sea la que se suministra con este sistema.
- Consulte el siguiente diagrama para ver el peso máximo de envío de retorno para cada sistema.



**Figura 1**  
 Coloque objetos punzantes en el envase.



**Figura 2**  
 Para cerrar, ajuste firmemente la cubierta sobre la abertura.

| Tamaño de envase | Sistema de un cuarto de galón | Sistemas de 1 galón |        |        |        | Sistemas de 2 galones |        | Sistemas de 3 galones |        |        |
|------------------|-------------------------------|---------------------|--------|--------|--------|-----------------------|--------|-----------------------|--------|--------|
| Modelo:          | 10100                         | 11000               | 11002  | 11003  | 12000  | 12002                 | 13000  | 13002                 | 13004  |        |
| Peso Máx.        | 5 lbs                         | 10 lbs              | 17 lbs | 25 lbs | 17 lbs | 25 lbs                | 25 lbs | 25 lbs                | 25 lbs | 25 lbs |

**PARA OBTENER ASISTENCIA O PEDIR COMPONENTES DE REEMPLAZO, LLAME AL 800.772.5657**

**CAPACITACIÓN E INSTRUCCIÓN PARA SU SISTEMA DE RECUPERACIÓN DE SHARPS®**

**Pida su nuevo Sistema de Recuperación de Sharps® (Sharps® Recovery System) antes que este envase esté lleno.**

1. Retire el (los) envase(s) del embalaje y colóquelos en el lugar (los lugares) donde van a usarse. Guarde todos los componentes para reembalar el Sistema en el momento de enviarlo.
2. Coloque los objetos punzantes o los materiales de riesgo biológico en los envase(s) (Fig.1).
3. Cierra la cubierta con un firme chasquido sobre la abertura (Fig. 2). Asegúrese de que la cubierta está firmemente sellada antes de embalarla para enviarla.
4. Una vez listos para enviar, coloque el (los) envase(s) en la bolsa de plástico y la caja. Selle bien la bolsa alrededor del (de los) envase(s) usando una tirilla de amarre.
5. Cierre las solapas de la caja y coloque la cinta adhesiva. Escriba la dirección del remitente encima de la caja.
6. Retire el formulario de seguimiento de la guía de carga de la bolsa de plástico ubicada en la parte exterior de la caja blanca de embalaje. Llène completamente la parte superior del formulario y firmelo. Retire la copia inferior del formulario y guárdela para sus registros. Vuelva a colocar las copias restantes del formulario en la bolsa de plástico con el código de barras hacia afuera. LA OFICINA DE CORREOS NO ACEPTARÁ SU CAJA SIN EL FORMULARIO DE SEGUIMIENTO DE LA GUÍA DE CARGA.
7. Si desea seguir el envío en línea, entre a su cuenta SharpsTracer en [www.sharpstracer.com](http://www.sharpstracer.com) e ingrese el número de la caja. Para inscribirse en este servicio gratuito, llame al 800.772.5657.
8. Lleve el paquete correctamente sellado a cualquier oficina de correos de los EE.UU., entréguela a su cartero(a) o solicite una recogida a domicilio en prioridad de su correo yendo a [www.sharpsinc.com](http://www.sharpsinc.com). NO INTENTE ENVIAR EL PAQUETE POR UPS o FedEx. El franqueo será pagado por Sharps Compliance.
9. Descargue su Prueba de Recuperación (Proof of Recovery) de su cuenta SharpsTracer en [www.sharpstracer.com](http://www.sharpstracer.com) dentro de 30-45 días.

**EN CASO DE EMERGENCIA O DE DESCUBRIMIENTO DE DAÑOS O FUGAS, LLAME AL 1.800.772.5657**

Para recibir más información referente al uso al que está destinado el Envase de Recolección de Objetos Punzantes (Sharps Collection Container), llame al 800.772.5657.

## Appendix B: California and Minnesota Guidance on Sharps Disposal

The State of California has published guidance documents on Sharps management and disposal at the following web pages:

<http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/>

“A Guide to Syringe Disposal”

English version:

<http://www.calrecycle.ca.gov/HomeHazWaste/sharps/Brochure.pdf>

Spanish version:

<http://www.calrecycle.ca.gov/HomeHazWaste/sharps/BrochureSpan.pdf>

The State of Minnesota has published guidance documents on Sharps management and disposal at the following web page:

<http://www.pca.state.mn.us/index.php/living-green/living-green-citizen/household-hazardous-waste/safe-disposal-options-for-needles-and-syringes.html>

## Appendix C: Additional Guidance on Sharps Management

<http://www.epa.gov/wastes/wyl/stateprograms.htm>

<http://www.safeneedledisposal.org/>

<http://www.epa.gov/wastes/nonhaz/industrial/medical/disposal.htm>

<http://www.calrecycle.ca.gov/HomeHazWaste/sharps/>

<http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm>

<http://www.pca.state.mn.us/index.php/living-green/living-green-citizen/household-hazardous-waste/household-hazardous-waste-home.html>

<http://www.bd.com/us/diabetes/page.aspx?cat=7002&id=10284>

[http://www.cvs.com/CVSApp/help/help\\_subtopic\\_details.jsp;jsessionid=48E92777AC1EFED5BA1EDB4976499763.commerce\\_102?subtopicName=Proper+disposal+of+medication+%26+Sharps&topicid=400037](http://www.cvs.com/CVSApp/help/help_subtopic_details.jsp;jsessionid=48E92777AC1EFED5BA1EDB4976499763.commerce_102?subtopicName=Proper+disposal+of+medication+%26+Sharps&topicid=400037)