

Instructions for Use
Version 1

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Be sure that you read, view the illustrations, understand their content, and follow these Instructions for Use before you apply the Brereton Barrier on a transdermal system (patch) or on your skin and properly place the patch over the barrier. Talk to your healthcare provider, pharmacist or our support team if you have any questions. 1 (888) Brereton. [this number is fictitious]



Small - Nominally = 10% Coverage of Fentanyl Patch



Medium - Nominally = 15% Coverage of Fentanyl Patch

Instructions for Use
Version 1

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Large - Nominally = 20% Coverage of Fentanyl Patch

Instructions for Use

Version 1

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Indications:

The Brereton Barrier is intended to block the transdermal flow of fentanyl from prescribed patches to the skin as a patient's / client's controlled tapering process. The barrier is placed directly on the patch upon the removal of its protective film prior to placing it onto the skin. See illustrations:

drawing representing the different barrier sizes

<u>Size</u>	<u>*%</u>
S Small	10
M Medium	15
L Large	20

Nominal percentage

Select the proper barrier size: (nominal percentage values)

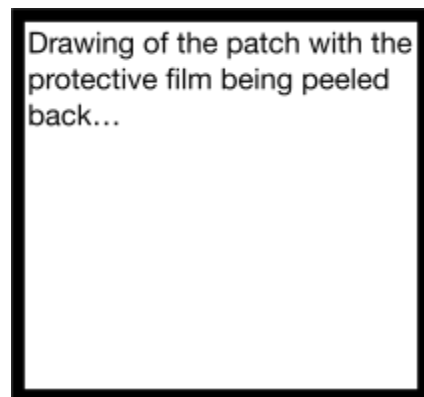
Small - **10%** barrier (nominal size)

Medium - **15%** barrier (nominal size)

Large - **20%** barrier (nominal size)

To select a 5% barrier; cut a Small [10%] barrier in half

1



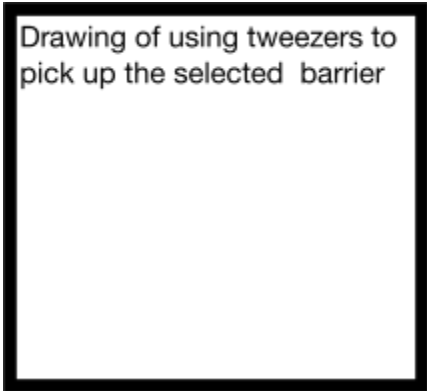
Follow the instructions that are provided with the fentanyl patch. Do not flush the protective film down the toilet. Discard the film in your trash can. When changing / renewing patches place the protective film in the envelope provided.

Instructions for Use

Version 1

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2



Drawing of using tweezers to pick up the selected barrier

To apply the selected [size] barrier, using the provided tweezers, pickup the barrier and carefully place it on the patch - horizontally.

3



Drawing of the barrier properly placed on the fentanyl patch

With the barrier properly placed on the patch proceed to following the fentanyl patch's manufacturer's instructions by placing the patch with the barrier now properly applied onto the skin - See illustration 4 and 5 - in the location (chest, hip, shoulder, etc.) you have chosen.

Instructions for Use

Version 1

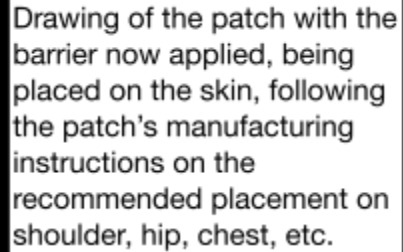
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Instructions for Use

Version 1

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4




Drawing of the patch with the barrier now applied, being placed on the skin, following the patch's manufacturing instructions on the recommended placement on shoulder, hip, chest, etc.

Following the patch's manufacturing instructions on the recommended placement of the patch on shoulder, hip, chest, etc.

5

Repeat the above steps and instructions upon replacing each used fentanyl patch with a new fentanyl patch. It is important to read and follow the instructions of the fentanyl patch manufacturer.



Drawing of the barrier and fentanyl patch being properly placed in the waste envelope.

DISPOSAL

At the prescribed conclusion of the fentanyl patch use (72 or 48 hours, as prescribed) and following the instructions from the manufacturer, carefully remove the used patch with the used Brereton Barrier still in place and using the supplied protective gloves and tweezers place it into the postage paid Brereton Barrier Waste Control envelope, seal the envelope and mail. Through your N Brereton Medical client logon portal notify N Brereton Medical by checking "Patch Waste Return" that the used patch with barrier still attached is being returned for proper control and disposal. Enter the envelope's control number along with the date of mailing and

logout.

CAUTION: DO NOT REUSE a Brereton Barrier. Do not flush the Brereton Barrier and / or the patch down the toilet. Always - keep Patch the Brereton Barrier away from children.

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Reporting of Incidents:

If during the use of the Brereton Barrier device or as a result of its use, a serious incident has occurred, please report it to N Brereton Medical Technologies, LLC and to your health care professional

Warnings

Reuse of a barrier once applied to a patch is not recommended and may conflict or negatively affect its tapering control over the transdermal flow of fentanyl and may as a result negatively affect your tapering success and time line. If you need additional barrier please log into your account and place your order.

Reprocessing, washing, disinfecting or sterilizing the barrier may compromise the product characteristics, causing additional risk of fentanyl transmission during your tapering process.

Cautions:

For any concern after reading these instructions over appropriate use, consult either the Wellness Coach at N Brereton Medical or your health care professional before you start using the Brereton Barrier.

Information:

Single use Brereton Barrier

The Brereton Barriers are intended to be stored in the container provided until removed for use, as the container protects the barriers and the label contains important information like batch code, and a unique barcode.

The Brereton Barrier may require removal prior to a MR scan, Xray or CT scan. Obtain advice from your health care professional and or the radiology technician prior to removal.

N Brereton Medical Technologies, LLC accept no liability for any injury or loss that may result if this product is used in a manner contrary to N Brereton Medical Technologies, LLC's current recommendations.

Storage Conditions:

Product may be stored either horizontally or vertically.

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Keep away from children.