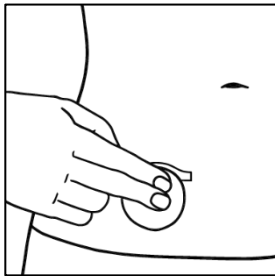
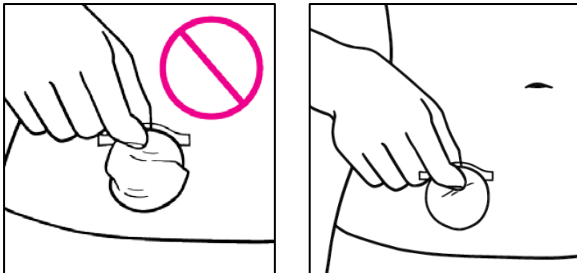


Step 4. Hold the small section of the liner and apply the sticky side of the patch to the chosen patch site.

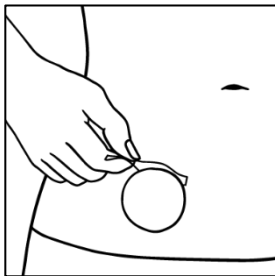


Step 5. Press the sticky side of the patch firmly onto your skin and smooth it down.

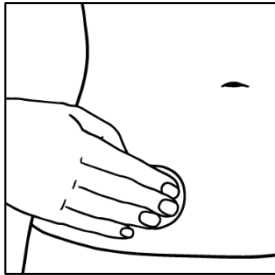
Avoid wrinkles or folds



Step 6. If the patch is not flat on the skin or there are large wrinkles, gently pull the patch off the skin while holding only the remaining protective liner and then put it on again.

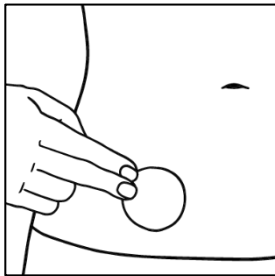


Step 7. After the patch is flat with no wrinkles, pull an edge of the remaining protective liner and gently pull it off.

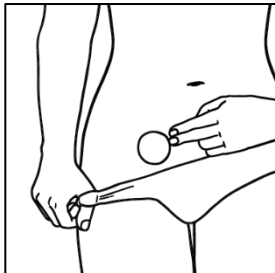


Step 8a. After the patch is on your body, press the entire patch firmly into place with your hand for 10 seconds, making sure the edges stick well.

Step 8b. Make sure the patch is on your skin all the way.



Step 9. The edges of the patch should be smoothed over with your finger and make sure there is good contact around the patch with your skin and make sure there are no wrinkles.



Step 10. It is important that you check the patch every day to make sure it is in the right place. The patch should be checked after any water exposure (such as bathing, showering, or swimming) to make sure it is in the right place because water may affect how well the patch sticks to your skin.

How do I throw away TWIRLA patches?

- To throw away your TWIRLA patch, fold the sticky side of the patch together and place in the trash right away so that children and pets cannot reach it. Do not flush used TWIRLA patches down the toilet.
- For more information on how to safely throw away medicines, see www.fda.gov/drugdisposal

When should I change the TWIRLA patch?

- TWIRLA is applied in a 4 week patch cycle. Each patch cycle includes 4 weeks (28 days). You will put on 1 patch every week for 3 weeks. You will not wear a patch during week 4. Each patch is worn for 7 days (1 week).
- Apply a new TWIRLA patch on the same day each week (this is called your Patch Change Day). For example, if you apply your first patch on a Monday, all of your TWIRLA patches should be applied on Monday.
- You will not wear a TWIRLA patch during week 4 (this is called your Patch Free Week). Make sure you remove the old patch from your body. Your period should begin during your Patch Free Week.
- After you have finished week 4, apply a new TWIRLA patch on the day after Week 4 ends. Repeat the patch cycle of 1 patch a week for 3 weeks followed by your Patch Free Week.

What if a patch starts to lift off your skin or completely comes off?

- If your patch starts to lift off your skin or completely comes off and you do not replace it, you may not get enough hormones to keep you from getting pregnant.
- If a patch starts to lift off your skin or is completely off for less than one day (up to 24 hours), you should try and put it on again to the same place or replace it with a new patch immediately. No back up birth control is needed and your **Patch Change Day** will remain the same.
- If a patch starts to lift off your skin or is completely off for more than 1 day (24 hours or more) **or** if you are not sure how long the patch has been not attached to your skin, you may not be protected from pregnancy. You should stop your current patch cycle and start over on a new patch cycle right away by putting on a new patch. The day you apply your new patch is now your new **Day 1** and your new **Patch Change Day**. Non-hormonal back up birth control, (such as condoms and spermicide, or diaphragm and spermicide) must be used for the first week of the new patch cycle.
- Do not put a patch on again if it is no longer sticky, if it has become stuck to itself or another surface or if it has other material stuck to it. If your patch cannot be put on again, a new patch should be put on right away. If you need help applying a patch, contact Agile Medical Information at 1-855-389-4752 or email: medicalaffairs@agiletherapeutics.com.

Can I wear the patch when I am exercising, or using a sauna, swimming pool, or whirlpool?

- Yes, women can maintain all their normal daily activities while using the patch.
- It is important to check your patch after any water that touches your patch during bathing, showering, or swimming, as prolonged water exposure may affect how well the patch sticks to your skin.
- If the patch starts to come off or completely lifts off the skin, try to put it on again.
- A patch should not be put on again if it is no longer sticky, if it has become stuck to itself or another surface or if it has other material stuck to it.

- If your current patch cannot be put on again, a new patch should be put on right away Before applying the patch, make sure your skin is clean and dry.
- Make sure you have not used any make up, creams, lotions, oils, powders or any other products on the skin area where you put or plan to put the patch. If you find yourself in need of an additional patch because you needed to replace a patch, contact Agile Medical Information at 1-855-389-4752 or email: medicalaffairs@agiletherapeutics.com.

What if you forget to change your patch (left your patch on more than 7 days)?

- **If you forget to change your patch at the start of any patch cycle (Day 1): You may not be protected from pregnancy.** You should apply the first patch of your new patch cycle as soon as you remember. This is now your new **Patch Change Day** and your new Day 1. You must use non-hormonal back up birth control (such as condoms and spermicide, or diaphragm and spermicide) for the first week of your new patch cycle.
- **If you forget to change your patch in the middle of the patch cycle (Day 8 or Day 15):** for 1 or 2 days (up to 48 hours): you should apply a new patch right away. The next patch should be applied on your usual **Patch Change Day**. No back up birth control is needed.
- **If you forget to change your patch for more than 2 days (48 hours or more): You may not be protected from pregnancy.** You should stop your current patch cycle and start a new 4week patch cycle right away by putting on a new patch. This is now your new **Patch Change Day** and your new **Day 1**. You must use non-hormonal back up birth control for the first week of your new patch cycle.

What to do if the patch starts to lift or the patch completely comes off from the skin and Late or Missed Patch Applications

Frequent Patch Situations	Will I have a New Patch-Change Day	Will I need to start a New 4week Patch Cycle	Will I need a backup Birth Control method
Did not apply patch on scheduled Day 1 of new patch cycle	Yes	Yes	Yes (for 7 days)
Patch not attached for less than 24 hours	No	No	No
Patch not attached for 24 hours or more, or unsure how long	Yes	Yes	Yes (for 7 days)
Less than 48 hours late for Patch Change Day (Day 8 or 15)	No	No	No
48 hours or more late for Patch Change Day (Day 8 or 15)	Yes	Yes	Yes (for 7 days)
Forgets to remove last patch on Day 22	No	No	No

What if you forget to remove your patch for the patch free week?

- **Past Day 22:** You should take it off as soon as you remember. No other change is needed. You should still start the next patch cycle on the usual **Patch Change Day**, which is the day after Day 28. No back up birth control is needed.

- **Your TWIRLA patch should never be off more than 7 days in a row. If you ever go more than 7 days without a patch, you should use another birth control method.**
- As with all hormonal birth control, the risk of getting pregnant increases with each day you go past the recommended 7day patch free period.

What if you wish to change your Patch Change Day?

- If you want to change your **Patch Change Day** you should complete your current patch cycle, removing the third patch on the correct day. During the Patch Free Week, you may select an earlier **Patch Change Day** by applying a new patch on the chosen day.

Your TWIRLA patch should never be off more than 7 days in a row.

Manufactured by:

Corium International, Inc.
4558 50th Street, SE
Grand Rapids, MI 49512

For more information call 1-855-389-4752 or email: medicalaffairs@agiletherapeutics.com.

This Instructions for Use has been approved by the U.S. Food and Drug Administration

Approved: February 2020