



Instructions for Use



Totally Needle-Free

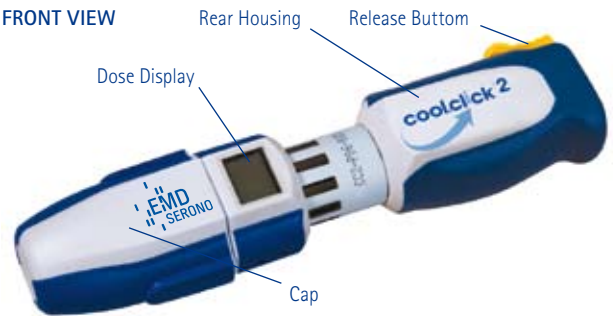
cool.click™ 2 Needle-Free
Growth Hormone Delivery Device

Exclusively for use with
EMD Serono Products containing Growth Hormone
[somatropin (rDNA origin) for injection]

RX only



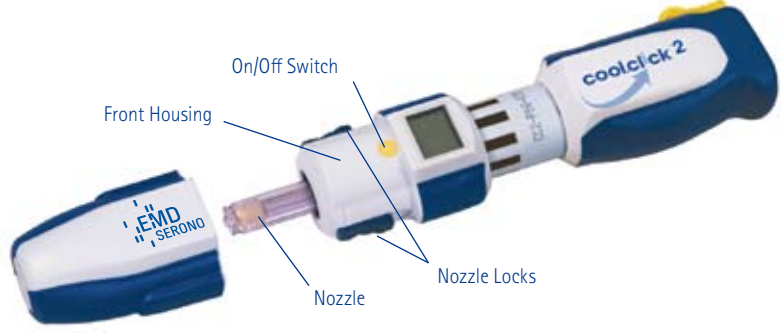
FRONT VIEW



REAR VIEW



CAP REMOVED



IN STORAGE BOX



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WELCOME TO cool.click™ 2 NEEDLE-FREE DELIVERY DEVICE

Your doctor has decided to treat you with a EMD Serono growth hormone medication that can be easily administered using cool.click™ 2, a needle-free delivery device.

cool.click™ 2 is a totally needle-free delivery device exclusively intended for the injection of EMD Serono growth hormone [somatotropin (rDNA origin) for injection].

cool.click™ 2 works by firing a jet of the liquid drug directly through the skin to the subcutaneous region. The jet is created through a powerful spring acting on a piston inside a nozzle, and the liquid is forced out through a small hole in the nozzle at high speed. Prior to each injection the spring must be charged by winding the device. The required dose is then drawn up into the nozzle, and then the device is discharged with the nozzle held against the skin by pushing the release button.

Before you get started with cool.click™ 2, please complete these easy steps:

- Thoroughly read this instructions for use before you practice using cool.click™ 2.
- Fold out the front cover of this instructions for use. You will find a photograph of cool.click™ 2 with each of its parts clearly labeled.

This instructions for use will show you how to use cool.click™ 2 with a practice cartridge (or vial) that comes in your Patient Starter Kit. After you are comfortable using the device on a pad, you'll learn how to administer your Growth Hormone medication using cool.click™ 2.

If you have any questions after reading this instructions for use, do not hesitate to ask your doctor or nurse, or call at Connections for Growth® toll free at 800-582-7989 or SerocareSM toll-free at 800-714-2437 for referral to the EMD Serono Nurse Network.

Remember, it is important that you feel confident with treatment right from the start.

WARNING

- The practice cartridge (or vial) liquid is not for injection in humans.
- Physician or nurse training should be provided to you before you or your child use this product.

- Parents must explain to their children that cool.click™ 2 is not a toy. Adult supervision is recommended when children are using cool.click™ 2.
- cool.click™ 2 must only be used with EMD Serono growth hormone and not any other brand of human growth hormone or medication.
- As with any injection device, improper use of cool.click™ 2 may result in injury, including the transmission of infectious blood-borne diseases. Adhere to strict safety and antiseptic precautions at all times.

CONTRAINDICATIONS

- In order to use cool.click™ 2 properly, you must first understand and follow the steps described in this instructions for use. It is important that you use cool.click™ 2 only as indicated and that you replace cool.click™ 2's disposable parts as often as recommended.
- Patients and children (with parental supervision) who use cool.click™ 2 by themselves must be able to see the numbers on the dose display clearly, turn the rear housing easily, and press the release button.
- cool.click™ 2 should not be used with patients and children who have low platelet counts, bruise or bleed easily, or are taking anticoagulants (blood thinners), or any other medication/therapy that may contribute to excess bleeding or bruising. Hemophiliacs should not use this device.
- cool.click™ 2 is not recommended for patients who do not have adequate subcutaneous tissue or normal hematopoietic function.
- cool.click™ 2 should not be used with patients for whom growth hormone is contraindicated. Please read the instructions for use or patient's information leaflet accompanying your prescribed growth hormone medication.
- If after trying a variety of delivery sites you are still unable to use cool.click™ 2 comfortably, contact your doctor or nurse.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

Section 1

GETTING STARTED WITH cool.click™ 2

WHAT YOU'LL LEARN

In this section, you'll learn:

- The name of each cool.click™ 2 part
- How to set the dose range of cool.click™ 2
- How to attach the nozzle and piston onto cool.click™ 2
- How to fill cool.click™ 2 with your dose
- How to practice using cool.click™ 2 with a practice cartridge (or vial)

WHAT YOU'LL NEED

- cool.click™ 2 device
- nozzle and piston*
- alcohol wipes*
- sterile gauze pad or cotton ball*
- practice cartridge (or vial)*
- click.easy™ Demokit*
- practice pad*

*Included in your Patient Starter Kit.

BEFORE YOU GET STARTED

It is important to know the names of all cool.click™ 2 parts. To learn each of the names, unfold the front cover of this instructions for use. You'll find a photograph of cool.click™ 2 with each part clearly labeled. Keep this page open as you learn how to use cool.click™ 2.

IMPORTANT

Always wash your hands thoroughly with antibacterial soap and water before using cool.click™ 2. Make sure to use a clean towel when drying your hands. Then place all of your cool.click™ 2 materials on a clean, dry surface.

Section 2

SETTING cool.click™ 2 FOR mg OR ml USE

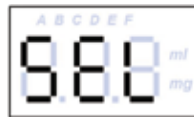
cool.click™ 2 has an LCD display for indicating the dosage. This can be set to read either milligram (mg) of growth hormone, Table 1, or milliliter (ml) of liquid dose, Table 2, which is specific to the EMD Serono growth hormone medication that your doctor has prescribed for you.

cool.click™ 2 can be set to one of six different dose ranges, indicated by the letters A to F at the top of the display. You doctor will tell you what setting you will need for cool.click™ 2.

Please ask your doctor or healthcare provider about setting the device.

CAUTION

- On delivery, cool.click™ 2 will be in a "null" mode, and when it is first switched on the display will show as in the figure below. No dose can be displayed until the dosage range has been set.



- You must set the dose range applicable for the EMD Serono growth hormone medication that your doctor has prescribed you. Please look carefully at Table 1 and Table 2 hereafter that list the various growth hormone medications. Search for your prescribed medication and note the corresponding setting (e.g. B, D, ml...).
- Then, to set the appropriate dose range, follow the instructions provided in the section entitled *Setting the dose range*.
- Your physician or nurse will set the device for you, do not set the device without guidance from a nurse or physician trainer.

Table 1 – Dosing in milligrams (mg)

GROWTH HORMONE PRODUCTS FOR USE WITH cool.click™ 2					
IMPORTANT: APPROPRIATE cool.click™ 2 SETTING SHOULD BE DONE UNDER THE DIRECTION OF A HEALTHCARE PROFESSIONAL ONLY					
cool.click™ 2 Setting Required	Product	Fixed Volume of Diluent (ml)	Fixed Concentration (mg/ml)	Milligram Dose Increments	Doses Feasible per Injection
B	Saizen® 8.8 mg click.easy™	1.51 ml	5.83 mg/ml	0.02 mg	0.30 – 2.92 mg
D	Saizen® 8.8 mg in vial	2.00 ml	4.40 mg/ml	0.02 mg	0.22 – 2.20 mg

Table 2 – Dosing in milliliters (ml)

GROWTH HORMONE PRODUCTS FOR USE WITH cool.click™ 2					
IMPORTANT: APPROPRIATE cool.click™ 2 SETTING SHOULD BE DONE UNDER THE DIRECTION OF A HEALTHCARE PROFESSIONAL ONLY					
cool.click™ 2 Setting Required	Product	Flexible Volume of Diluent (ml)	Concentration Range (mg/ml)	Milliliter Dose Increments	Doses Feasible per Injection
ml	Saizen® 5 mg in vial	1.0 – 3.0	1.67 – 5.00 mg/ml	0.01 ml	0.08 – 2.50 mg
ml	Saizen® 8.8 mg in vial	2.0 – 3.0	2.93 – 4.40 mg/ml	0.01 ml	0.15 – 2.20 mg
ml	Serostim® 4 mg in vial	0.5 – 1.0	4.00 – 8.00 mg/ml	0.01 ml	0.20 – 4.00 mg
ml	Serostim® 5 mg in vial	0.5 – 1.0	5.00 – 10.00 mg/ml	0.01 ml	0.25 – 5.00 mg
ml	Serostim® 6 mg in vial	0.5 – 1.0	6.00 – 12.00 mg/ml	0.01 ml	0.30 – 6.00 mg

Setting the dose range

1. With the cap in place, hold the cap and front housing in one hand and the rear housing in the other hand. Rotate the rear housing so that the rear housing moves toward the front housing as far as it will go. You may notice a slight click as the device engages.



2. Remove the cap and switch on the dose reading by pressing the yellow ON/OFF switch.



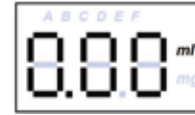
3. Take the special dose setting key (you will find it inside the front cover of this instructions for use) and insert into the front housing as shown, until it stops with both prongs fully pushed and then withdraw the key immediately.



4. The display will start to flash, indicating that dose setting mode is active.

5. Press the yellow ON/OFF switch. The display will indicate 0.00 with "ml" flashing. Press the ON/OFF switch again and the display will show "mg" plus "A" flashing. Repeat this until the required setting is shown. On each press of the ON/OFF switch the display will step through the following sequence and repeat:

SEL → ml → A mg → B mg → C mg → D mg → E mg → F mg → (repeat)



- Please note: if you press and hold the yellow ON/OFF switch too long the display will turn off.
6. Once the required setting is shown, push the key in again and then withdraw the key. The display will briefly blank and then stops flashing. This confirms the setting, and the device returns to normal operation mode. The setting will now be displayed and will remain programmed into the device until it is changed in this way again, even if the battery is removed.

WARNING

- Before starting to inject your growth hormone medication ensure that the appropriate dose range is set properly. Injecting with cool.click™ 2 set to a wrong dose range will deliver wrong doses of the growth hormone medication.
- If you are not sure of setting the right dose range ask your doctor or nurse.
- Do not attempt to modify or reset the dose range at any time, unless required by your doctor or nurse.
- Each time you will deliver your growth hormone medication with cool.click™ 2 check that the right dose range letter is displayed.

CAUTION

- Once the setting of the dose range is correctly done please keep the dose setting key in a safe place. You will not need it anymore, unless your doctor prescribes for you a different EMD Serono growth hormone medication. Key will be needed for changing the battery.
- Pay careful attention to when nozzle and piston must be replaced and discarded. See section 5, "Maintenance and Care", for information on how to change the nozzle and piston.

Attaching the nozzle and piston

☞ Please refer to the Instruction for Use accompanying your nozzle and piston pack before starting using nozzle and piston.

1. First peel open the blister pack containing the nozzle and piston assembly. Remove the assembly.
2. With the cap in place, hold the cap and front housing in one hand and the rear housing in the other hand. Rotate the rear housing so that the rear housing moves toward the front housing as far as it will go. You may notice a slight click as the device engages (see figure in the section "Setting the Dose Range").
3. Remove the cap, and pull back the nozzle locks against the spring as shown.



4. Holding the nozzle locks back, introduce the nozzle and piston assembly to the opening in the cool.click™ 2 as shown.



5. Push the nozzle firmly so that the piston clicks into place in the cool.click™ 2.
6. Release the nozzle locks, and ensure that they move forward fully. You will notice a "click".


IMPORTANT

If it doesn't click, gently push the nozzle into the device until the nozzle locks spring forwards.



7. Check that the nozzle is correctly fitted by pulling it and making sure that it stays in the device. Once locked into position, it is important that a nozzle is installed only once, to avoid breakage.

CAUTION


- Thoroughly read the Instruction for Use accompanying your nozzle and piston pack for a proper use of nozzle and piston with your cool.click™ 2 device.
- The nozzle and piston are supplied as a pre-assembled accessory in a sterile blister pack. Check that the expiry date (indicated by the sandglass symbol ) has not expired. Do not use the nozzle and piston assembly if the blister pack is open or appears damaged.
- The nozzle and piston are fitted to the cool.click™ 2 together.

- Ensure that the nozzle locks have moved fully forwards after having attached the nozzle and piston to cool.click™ 2.
- Do not touch the ends of the nozzle or allow them to touch any surface. Hold the nozzle by its sides.
- Do not share nozzle and piston between individuals.
- Dispose of used nozzle and piston with care. Do not reuse or re-sterilize nozzle and piston after removal from cool.click™ 2.

Fitting the cartridge connector or the vial connector

Depending on the EMD Serono growth hormone medication that is prescribed for you the reconstituted solution of the medication will be either in a cartridge or in a vial. For full information on how to reconstitute and prepare your growth hormone medication please read thoroughly the Instruction for Use that will come within the pack containing your cool.click™ 2 accessories, either your cartridge connector pack or your reconstitution kit pack.

In order to draw the reconstituted solution of growth hormone from a cartridge or from a vial you have to use a connector, which is supplied as an accessory in a sterile blister pack. Do not use the connector if the blister pack is open or appears damaged.

1. Prior to using either cartridge connector or vial connector check that the expiry date (indicated by the sandglass symbol ) has not expired.
2. Then fit either cartridge connector or vial connector to the cartridge or vial containing the reconstituted solution of your growth hormone medication as described in the aforementioned Instruction for Use.

Once this is done you are ready to fill cool.click™ 2 with your dose.

CAUTION

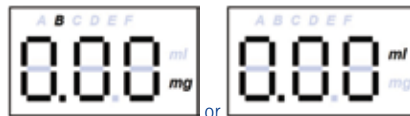
Thoroughly read the Instruction for Use accompanying your cartridge connector pack or your reconstitution kit pack for a proper use of either cartridge connector or vial connector with your cool.click™ 2 device.

Filling your dose

1. With the cap in place, hold the cap and front housing in one hand and the rear housing in the other hand. Rotate the rear housing so that the rear housing moves toward the front housing as far as it will go. You may notice a slight click as the device engages.



2. Remove the cap and press the yellow ON/OFF switch. The display will switch on and show 0.00, the dose unit "mg" (or "ml") and the dose range setting (A to F) as appropriate.



- ⚠ Please note: if the display shows 8.8.8 flashing as in the picture hereafter, further tighten the rear housing.



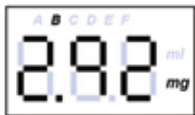
3. Remove the protective cap from the cartridge connector (as shown) or vial connector.



4. Connect the nozzle to the cartridge connector (as shown) or vial connector.



5. Hold the cool.click™ 2 vertically with the cartridge or vial uppermost and the display facing you. Rotate the rear housing such that the piston will begin to draw the solution of your growth hormone medication into the nozzle. The display will indicate the dosage drawn. For example the figure hereafter indicates 2.92 mg in dose range "B".



6. Once the required dose is indicated on the display, wind one full turn further past the required dose setting. If there are any air bubbles present in the nozzle, tap it gently with your fingers to release the air bubbles. Then wind back until the required dose is indicated on the display.

If there is still air bubbles present, wind one full rotation again, tap gently and wind back to the required dose. Repeat until all air bubbles are gone.



7. Remove the nozzle from the cartridge connector (as shown) or vial connector and re-fit the protective cap onto cartridge or vial .



The cool.click™ 2 is now ready to deliver the injection.

IMPORTANT

- If you overfill cool.click™ 2 past your specific dose, simply wind back until the required dose is indicated on the display.

CAUTION

- Always look at the liquid inside the nozzle. The space between the piston tip and the end of the nozzle should be filled with liquid and not air bubbles. If you see air bubbles in the nozzle, remove them by repeating the operation described above in the "Filling your dose" section.

- Never discharge the device without a nozzle in place.
- Never discharge the device if the nozzle is empty.
- Never discharge the device if the liquid in the nozzle has air in it.
- Do not attempt to dismantle the device.

Section 3 DEMONSTRATION AND PRACTICE

To practice with cool.click™ 2 use the practice cartridge from the click.easy™ Demokit that you'll find in your Patient Starter Kit.

1. Peel open the blister pack containing a cartridge connector that you will find in your Patient Starter Kit.
2. Fit the cartridge connector to the practice cartridge . Please refer to the Instruction for Use accompanying the cartridge connector pack to do the operation properly.
3. Then fill the nozzle with a dose of practice solution by following the instructions in the section "*Filling your dose*".

USING THE PRACTICE PAD

The first time you practice with cool.click™ 2, use the practice pad that came in your Patient Starter Kit.

1. Supporting the practice pad with one hand, hold the handgrip on the rear housing of cool.click™ 2.
2. Place the nozzle against the pad and push the rear housing towards the pad just hard enough to create a slight dimple. Make sure the entire surface of the nozzle is in contact with the pad, and hold cool.click™ 2 still—firmly, but not hard. You will feel the rear housing slide forwards slightly. Note that the rear housing must be in this position before the delivery can be made.

Note: without downward or forward pressure the device will not fire. This is a safety feature. It will prevent the device from firing if injection button is accidentally hit or bumped.



3. Maintain this pressure on the pad and hold cool.click™ 2 still. Then press the release button. This will deliver the dose. Delivery takes less than a second. Hold the nozzle against the pad, maintaining the pressure, for approximately 3 seconds before removing.



WARNING

- DO NOT INJECT THE PRACTICE LIQUID INTO HUMANS.

CAUTION

- Remember, never press the release button unless liquid is visible in the nozzle.

IMPORTANT

- Use the practice pad to practice delivery of the dose using the practice liquid as many times as necessary in order to feel comfortable using cool.click™ 2.
- Once you feel comfortable using cool.click™ 2 practicing with practice solution, you are ready to administer your prescribed EMD Serono growth hormone medication (Section 4).

WARNING

- When you have finished using cool.click™ 2 with practice solution, replace the nozzle and piston before you proceed with delivering your growth hormone medication.

Section 4

DELIVERING YOUR DOSE OF EMD Serono GROWTH HORMONE [somatotrin (rDNA origin) FOR INJECTION]

WHAT YOU'LL LEARN

In this section, you'll learn:

- how to choose an injection site
- how to fill cool.click™ 2 with your dose of growth hormone
- how to deliver your dose of growth hormone with cool.click™ 2

WHAT YOU'LL NEED

- cool.click™ 2 device
- cartridge or vial with reconstituted solution of your prescribed EMD Serono growth hormone.
- Alcohol prep pad

How to deliver your dose of growth hormone with cool.click™ 2

Before delivering growth hormone with cool.click™ 2, be sure you are trained in using cool.click™ 2, as described in section 3, "Demonstration and Practice". You should use cool.click™ 2 for the administration of your EMD Serono growth hormone medication only after you are comfortable using the device.

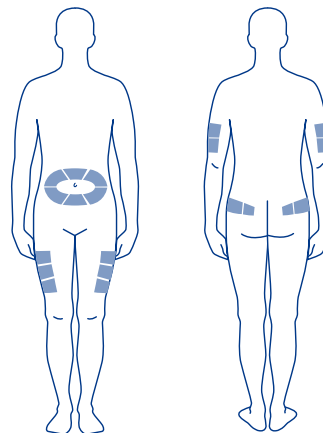
Choose an injection site

Decide where on your body to deliver the dose of growth hormone. Your doctor or nurse will recommend what areas should be used and how often those areas should be rotated.

Your doctor or nurse may recommend using cool.click™ 2 at these delivery sites:

- **Abdomen:** use the areas around the bellybutton, an inch or two away.
- **Legs:** select a fleshy area on the front or side of the thigh. Be seated with both feet on the floor or with one leg crossed over the other.
- **Rear End:** be seated on chair and lean forward. Use the upper, outer section of your rear end.
- **Arms:** be seated on a chair, and find a position where you can comfortably reach a fleshy area on the back of the arm.

Keep a record of which part of the body you select every time you use cool.click™ 2.



Fill Your Dose

Using your cartridge or vial of reconstituted solution of growth hormone repeat carefully the same steps done described in the "Filling your dose" section.

Deliver the dose of EMD Serono growth hormone

1. Clean the delivery site with an alcohol wipe using a circular motion. Wait for the skin to dry before using cool.click™ 2.

2. Hold the handgrip on the rear housing of cool.click™ 2. Place the nozzle against the skin at the chosen injection site and push the rear housing towards the injection site. You will feel the rear housing slide forwards slightly. Note that the rear housing must be in this position before the delivery can be made.

Note: without downward or forward pressure the device will not fire. This is a security feature. It will prevent the device from firing if injection button is accidentally hit or bumped.



3. Maintain this pressure on the injection site so that the skin is slightly depressed and has a slight dimple. Press the release button firmly. This will deliver the injection. Delivery takes less than a second. You may experience a slight sensation as the delivery is made.



4. Hold the nozzle against the skin, maintaining the pressure, for approximately 3 seconds before removing.

It is normal to observe slight pinprick bleeding after delivery. A raised white bump on the skin immediately after delivery indicates that the delivery was dermal instead of subcutaneous, and wetness around the delivery site indicates incomplete delivery. Both can be caused by

using insufficient pressure of the nozzle against the skin, or movement of the nozzle during delivery. It is important that the delivery technique is corrected to avoid such conditions.

☞ Please refer as well to the section "What to do if you have a skin reaction", Section 6.

5. After delivering the dose, hold pressure on the site for 30 seconds using three fingers over a sterile gauze pad.



IMPORTANT

- Inject your dose immediately after having filled the nozzle with the growth hormone solution. If you leave cool.click™ 2 sitting for more than 5 minutes the device will go into a rest mode with a blank display. You may reactivate the display by pressing the yellow ON/OFF switch and you can still administer your dose. If you leave cool.click™ 2 sitting for more than 15 minutes the device will turn off. You may switch on the device by pressing the yellow ON/OFF switch. However the display will show its initial status with "8.8.8" flashing. You can still administer your dose.
- Never press cool.click™ 2's release button without the nozzle attached.
- Never press cool.click™ 2's release button with air bubbles inside the nozzle.
- Do not overfill cool.click™ 2 past your specific dose. If you do, move all of the liquid back into the cartridge or into the vial and re-set the correct dose.
- Always discard the nozzle and piston according to the Instruction for Use accompanying the nozzle and piston pack.
- Always fit the cap fully on the cool.click™ 2 when not in use.

- Safely dispose of used nozzle and piston as directed by your healthcare provider. Do not reuse or re-sterilize after removal from cool.click™ 2.

WARNING

- Do not share the same nozzle, piston, cartridge connector or vial connector between different individuals.
- As with any injection device, improper use of cool.click™ 2 may result in injury, including the transmission of infectious blood-borne diseases. Adhere to strict safety and anti-septic precautions at all times.

CAUTION

- Hold cool.click™ 2 in place against the skin for 3 seconds after pushing the release button to ensure proper delivery and avoid delivery site reactions.
- Do not pinch the skin when delivering the dose.
- To avoid injury or damage to cool.click™ 2, only press cool.click™ 2's release button when the device is filled with the prescribed amount of liquid.

Section 5

MAINTENANCE AND CARE

WHAT YOU'LL LEARN

In this section, you'll learn:

- how to store cool.click™ 2
- how to change the nozzle and piston
- how to replace the battery

How to store cool.click™ 2

After delivering your dose with cool.click™ 2 proceed with the following steps:

1. Press continuously the yellow ON/OFF switch until the display electronics shut down. In any case the display electronics will shut down automatically after approximately 5 minutes, thus preserving the battery life.



2. Clean the end of the nozzle with an alcohol wipe or, if required, remove the nozzle and piston and discard it (refer to the Instruction for Use accompanying your nozzle and piston pack about when and how often you must change the nozzle and piston).
3. Place the cap back on cool.click™ 2 and store in its storage box at room temperature and in a safe place indoors.



CAUTION

- Avoid storage at low temperature (below 50 °F / 10 °C) or high temperature (above 104 °F / 40 °C).
- Avoid storage in a high humidity environment such as bathroom or sauna.
- Keep cool.click™ 2 clean. You can clean the body of the device with a damp cloth and mild detergent. Dry well.
- Never submerge cool.click™ 2 in water. The inside of the device should never get wet.

- Never place cool.click™ 2 in the refrigerator and never leave it exposed to direct sunlight for a long time.
- Always store cool.click™ 2 in its storage box when not used and for travel.
- Replace cool.click™ 2 after three years of use or sooner if the device functions improperly. For replacement information, please call EMD Serono's Connections for Growth® toll-free at 800-582-7989 or SerocareSM toll-free at 800-714-2437.

How to change the nozzle and piston

CAUTION

- Please follow strictly the Instruction for Use accompanying your nozzle and piston pack about when and how often you must change the nozzle and piston.
1. In order to remove the nozzle, pull back the nozzle locks and withdraw the nozzle. This will expose the piston.



2. Safely dispose of the nozzle.
3. Remove the piston by pushing to one side so that it snaps out of the cool.click™ 2.



4. Safely dispose of the piston.

The cool.click™ 2 is now ready for fitting a new nozzle and piston assembly.

How to replace the battery

The cool.click™ 2 is supplied with a battery installed..

However, should the battery getting low, the display will show either:

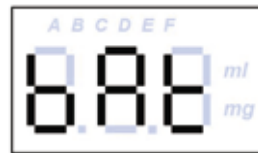
"0.00" and "bAT" flashing alternatively, when you switch cool.click™ 2 on, in accordance to step 2 in the section "Filling your dose"

or

"8.8.8" and "bAT" flashing alternatively, when you are already operating cool.click™ 2.

This warns that the battery needs to be replaced. Nevertheless you can still continue to operate cool.click™ 2 normally and to inject your dose.

Should the battery getting low and the display shows "bAT" steadily, and it will not be possible to operate cool.click™ 2. The battery must be replaced before you can operate cool.click™ 2 and inject your dose.



To replace the battery perform as instructed hereafter:

1. Use the dose setting key supplied with the device, which was used for setting the dose range, to withdraw the battery housing.
2. Remove the battery and fit a new CR2032 coin cell battery (3V lithium), making sure that the orientation is the same as the old battery

3. Push the battery housing back into place until it clicks. This process is shown below.



IMPORTANT

Do not throw away the battery with household waste. Dispose of the used battery through proper recycling methods.

Section 6

Frequently Asked Questions (FAQs)

WHAT YOU'LL LEARN

In this section, you'll learn:

- how cool.click™ 2 works as well as some useful tips on how to overcome any slight problems that you may encounter when using cool.click™ 2

and furthermore:

- what to do if you are experiencing bruising or stinging
- what to do if your skin is wet after delivering a dose
- what to do if you see bubbles in reconstituted solution of growth hormone
- what to do if you have a skin reaction

How does cool.click™ 2 inject growth hormone?

The rear housing of cool.click™ 2 is rotated to wind up a spring that is used to power the device. The discharge of the spring forces a fine stream of the growth hormone solution through an

orifice in the nozzle at high pressure, so that the growth hormone solution penetrates the skin and injects it to the subcutaneous layer of tissue.

The potential problems that you may encounter with cool.click™ 2 can usually be overcome just by ensuring that your injection technique is correct.

You may need to practice several times in order to perfect your technique to ensure a comfortable, complete injection. The main points to consider when perfecting your injection technique are:

- Was the tip of the nozzle firmly pressed against the injection site at 90° to the skin surface?
- Was the cool.click™ 2 kept still throughout the injection?
- Was the cool.click™ 2 held in position for 3 seconds following injection?
- Did you remember to rotate the cool.click™ 2 one full rotation past your dose before winding back to the correct amount?
- Did you check the nozzle was free from air bubbles prior to injection?
- Was the nozzle wiped with an alcohol wipe before storing or after use?
- Has the nozzle and piston been changed according to guidelines or recommendation?

If you are confident your technique was good, try using other injection sites.

What to do if you are experiencing bruising or stinging

If you are experiencing bruising or stinging when using cool.click™ 2, check the following:

- You might be pushing nozzle too hard against the skin. You only have use enough pressure to push the rear housing towards the injection site.
- Your muscles may be too tense. Attempt to relax yourself or encourage your child to relax. It may be helpful to use distractions such as headphones or television.
- You may be choosing a site that contains more muscle than fat. Review the suggested delivery sites –in section 4, "Choose an injection site".
- The nozzle may be partially clogged and may need to be replaced.

If these suggestions do not solve your bruising or stinging problem, call Connections for Growth® toll free at 800-582-7989 or SerocareSM toll-free at 800-714-2437 for referral to the EMD Serono Nurse Network or consult your doctor or nurse.

What to do if your skin is wet after delivering a dose

Some moisture at the delivery site or a small amount of fluid, equivalent to what you might see at the tip of a needle, is normal. If you see excessive moisture, ensure that your injection technique is correct by following the instructions for use. Check particularly the following:

- You might be moving cool.click™ 2 during delivery. Hold cool.click™ 2 steady while you press the release button.
- You might be moving cool.click™ 2 away too soon after delivery. Keep it in place for at least three seconds after you press the release button.

If moisture persists, you may talk to your doctor or nurse about technique.

What to do if you see bubbles in reconstituted solution of growth hormone

Always look at the liquid inside the nozzle after filling cool.click™ 2. The space between the tip of the piston and the end of the nozzle should be filled with liquid and not air bubbles.

CAUTION

If you see air bubbles in the nozzle, wind one full turn further, then tap it gently to release bubbles and then wind back until the required dose is indicated on the display. If there is still air present, repeat until all air is expelled.

What to do if you have a skin reaction

Normally cool.click™ 2 produces a momentary sensation during delivery. It may be totally painless or you may feel a pressure sensation or slight flick. It is normal to observe:

- slight moisture
- minor bleeding
- a raised, white bump the size of a pinhead
- white or reddish area

Uncommon reactions you should watch out for include:

- a large, white, raised bump at the delivery site, see figure hereafter

- significant liquid leaking or dripping at the delivery site



Often, these reactions are caused by improper technique. If you see any of these reactions, review this instructions for use, talk to your doctor or nurse, or call EMD Serono Connections for Growth® toll-free at 800-582-7989 or SerocareSM toll-free at 800-714-2437.

IMPORTANT

- If the nozzle gets clogged, simply replace it with a new nozzle and piston set.
- If your cool.click™ 2 doesn't work properly, call EMD Serono Connections for Growth® toll-free at 800-582-7989 or SerocareSM toll-free at 800-714-2437 for a replacement.

Section 7 RESOURCES

THE EMD SERONO PATIENT ASSISTANCE AND GROWTH SUPPORT™ PROGRAMS.

Growth disorders can raise many questions and concerns for patient families and caregivers – from how to use medication properly to insurance reimbursement. Through the Connections for Growth® and SerocareSM programs in the US, EMD Serono provides information and services to help parents and their children, including:

- educational materials
- reconstitution and dosage information
- reimbursement support
- contact information for your local nurse in the EMD Serono Nurse Network

EMD Serono representatives will help you with reimbursement and billing issues.

Connections for Growth® and SerocareSM provide referrals to the EMD Serono Nurse Network in your area. Nurses in the Nurse Network can answer your questions about proper use and maintenance of cool.click™ 2, and can help you work through any problems you may experience.

Connections for Growth® Toll-free: 800-582-7989 (US) • Website: www.howkidsgrow.com

SerocareSM Toll free: 800-714-2437 (US) • Website: www.serostim.com.

Section 8 QUICK GUIDE

HOW TO DELIVER YOUR DOSE

Using cool.click™ 2 – Preparation and Delivery

1. Rotate the rear housing to move toward the front housing as far as it will go. A slight click may be heard.



2. Switch on the device, the display should show 0.00. If the display shows 8.8.8 flashing, further tighten the rear housing.



3. Connect the nozzle to the cartridge connector (as shown) or vial connector.



4. Draw the solution of growth hormone medication into the nozzle. The display will indicate the dosage drawn.



5. Wind one full turn past your dose setting and release any air bubbles in the nozzle by tapping gently with your finger.



6. Wind back to your required dose. If air bubbles are still present in the nozzle, repeat step 5 until all air bubbles are gone.

7. Remove the nozzle from the cartridge connector (as shown) or vial connector; the device is ready to deliver.



8. Clean the injection site with an alcohol wipe and wait for the skin to dry before using click™ 2.

9. Place the nozzle against the skin at your chosen injection site and press the release button firmly. Forward or downward pressure is needed for device to fire.



10. Hold the nozzle against the skin for approximately 3 seconds before removing.

11. After delivering the dose, hold pressure on the site for 30 seconds using a sterile gauze pad.



12. Clean the nozzle with the alcohol wipe. Recap device and store in its carrying case.

HELPFUL TIPS

- Get supplies lined up on a clean, dry surface:
 - cool.click™ 2 device
 - nozzle and piston set
 - cartridge connector or Reconstitution Kit
 - Sterile gauze pad or cotton ball
 - alcohol wipe or prep pad
- Never press the cool.click™ 2 release button without the nozzle attached
- Never press the cool.click™ 2 release button with air bubbles inside the nozzle
- Always look at the liquid inside the nozzle. The space between the piston tip and the end of the nozzle should be filled with liquid and not air bubbles.
- If you overfill cool.click™ 2, simply move all the liquid back into the cartridge or vial and re-set to your correct dose.
- Always place the cap fully on the cool.click™ 2 when not in use.
- Please read Instructions for use for complete instructions, warnings, and important information.
- Please see full prescribing information for your product.
- Questions:
 - Call EMD Serono Connections for Growth® toll free at 800-582-7989 or SerocareSM toll free at 800-714-2437
- Websites:
 - howkidsgrow.com
 - saizenus.com
 - serostim.com



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PCT-193 L3-0308