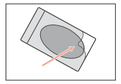
brella®

**Brella® Patch**
**Instructions For Use**

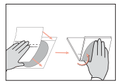
## Quick Guide: Brella® Patch Use

**Step 1: Prep**
Ensure the patient is sweating, position the patient with underarm as flat as possible, and dry the treatment area.

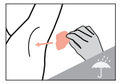


**Step 2: Apply Patch and Massage**
Open Brella® packet, remove release liner, and apply Brella® patch.


Start timing. Gently massage the treatment area, continually assessing the patient for pain or discomfort.



**Step 3: Remove and Deactivate Patch**
Remove patch when treatment is complete (up to 3 minutes, or sooner if pain elevates to 8/10). Cover the patch with filter paper, and fold in half with filter paper on the inside. Deactivate the patch by placing in the deactivation container.



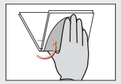
**Step 4: Clean Axilla**
Using water-soaked gauze, gently wipe treated area until no residue remains.

**Step 5: Repeat Steps 1–4 on the Other Axilla**

**Step 6: Dispose of the Deactivated Patches**
Set aside for at least 1 hour, then dispose of deactivation kit according to federal, state, and local regulatory requirements. (See "Deactivate Brella® Patch" section below).

## Quick Guide: Deactivate Brella® Patch

Immediately after removing each patch from axilla, press filter paper onto patch to cover sodium and adhesive.



Fold in half along dotted line with filter paper facing inwards.

Place folded patch into deactivation container, and press lid closed until it clicks.

**Note:** One patch per container.

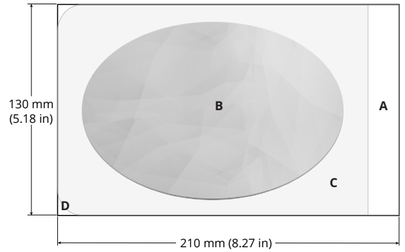

Set aside for at least 1 hour, then dispose of deactivation kit according to federal, state, and local regulatory requirements.

## Device Description

Brella® is a non-invasive, single-use, energy-based patch. When the active material (sodium) contacts sweat, thermal energy is produced. This temporarily inactivates sweat glands leading to a reduction in sweat production.

The patch consists of a thin solid layer of sodium mounted on an adhesive backing and covered by a protective release liner. The release liner protects the patch and the adhesive during storage and handling and prevents environmental exposure of the active material prior to use. The adhesive backing holds the patch in place during the treatment, and includes a release tab for removal and handling. (See Figure 1)

**Figure 1: Brella® Patch**




**A.** Release tab **B.** Sodium layer (active material) **C.** Adhesive backing **D.** Release liner

The non-sterile patch is packaged in an impermeable, argon filled, foil pouch. The packaging protects the patch during transit and storage. A deactivation kit is provided with each patch to deactivate for disposal after use.

## Indications for Use

**Brella® is indicated for treatment of primary axillary hyperhidrosis in adults.**

⚠ **CAUTION:** UNITED STATES LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

## Contraindications

**Brella® is contraindicated in patients:**

- who present with an active skin irritation or disease at the treatment site.
- who present with any abrasions, nicks, or cuts at the treatment site at the time of treatment.

## Summary of Clinical Data

The pivotal study was a randomized, double-blinded, sham-controlled, pivotal study that enrolled 120 total participants who had gravimetric sweat production (GSP) of ≥50mg/5min, a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4, and a medical history consistent with primary axillary hyperhidrosis. Efficacy (sweat reduction) was monitored by assessing HDSS and GSP values. The primary endpoint was based on post-treatment HDSS scores of 1 or 2 at 4-weeks in the active vs. sham control groups. Secondary endpoints were the 4-week assessment of: the QoL measures of Bother and Impact; the improvement of HDSS by 2 points; and the reduction in GSP by ≥50%.

The treatment was overall well-tolerated, with no serious adverse events. The presence of deep creases in the axilla, striae, thickened/macerated or wet epidermis, or prominent perifollicular papule increased the risk of an adverse skin reaction. In total, 22% (14/63) of Brella® (N-SWEAT Patch) treated subjects experienced a Device-Related event. All adverse events were considered Mild to Moderate and resolved without sequalae. Most were local skin reactions and included pain/stinging, redness, small skin abrasions, swelling, or ulceration. A single instance of compensatory hyperhidrosis was reported.

Efficacy was demonstrated by a reduction in sweat in participants treated with the active device compared to participants treated with the sham device. For the primary endpoint, 64% active vs. 44% sham (p=0.0332) achieved HDSS 1 or 2 at 4-weeks after treatment with the active patch vs. the sham patch.

Secondary endpoint analysis demonstrated greater 2-point improvement in HDSS in the active vs. sham groups at 43.2% vs. 16.3% (p=0.0107). A reduction in GSP of ≥50% was demonstrated in 60.5%, meeting the endpoint of ≥50% responder rate. The mean change in GSP was -57.3 and -18.2 mg/5min for the active and sham subjects respectively (p=0.0036). Impact on quality of life (QoL) secondary endpoints demonstrated reduction in Bother score (-1.52 active vs. -0.61 sham (p=0.0005)) and Impact score (-1.44 active vs. -0.57 sham (p=0.0004).

The duration of effect showed that a substantial number of patients did not return to baseline HDSS for up to 14 weeks post treatment (47.7% active vs. 27.9% sham) with 43.0% of active subjects still responding at 16 weeks.

Safety and effectiveness have not been tested for multiple treatments or exposures to the patch, or other body areas.

## Storage

Brella® should be stored in the provided box in a dry, clean location, and within the temperature limits stated on the packaging.

⚠ **CAUTION:** DEACTIVATE AND DISCARD PATCHES THAT HAVE PASSED THE EXPIRATION DATE BY FOLLOWING THE "DEACTIVATE PATCH" INSTRUCTIONS. SAFETY AND EFFECTIVENESS OF THE DEVICE HAS NOT BEEN ASSESSED PAST THE EXPIRATION DATE.

## Warnings & Precautions

### General Warnings

**WARNINGS DESCRIBE SERIOUS ADVERSE REACTIONS AND POTENTIAL SAFETY HAZARDS.**

**WARNING:** DO NOT TOUCH YOUR EYES WHEN HANDLING BRELLA®. RESIDUAL SODIUM OR SODIUM HYDROXIDE MAY CAUSE PERMANENT EYE DAMAGE.

**WARNING:** THE ALKALI METAL ON BRELLA® MAY BE FLAMMABLE IF IT CONTACTS WATER, ALCOHOL, OR OTHER FLUID CONTAINING WATER. PRECAUTIONS SHOULD BE TAKEN TO ENSURE NO WATER CONTACTS BRELLA®.

**WARNING:** DO NOT DEACTIVATE BRELLA® IN AN AREA CONTAINING FLAMMABLE MATERIAL OR GASSES (SUCH AS AEROSOLS OR COMBUSTIBLE LIQUIDS, INCLUDING ALCOHOL OR NAIL POLISH REMOVER) OR ACCELERANTS (E.G., OXYGEN OR NITROUS OXIDE).

**WARNING:** CONTACT WITH MOISTURE OR IMPROPER DISPOSAL OF BRELLA® MAY RESULT IN FIRE. IF THE BRELLA® CATCHES FIRE, ISOLATE, THEN EXTINGUISH WITH PROPER FIRE SUPPRESSION EQUIPMENT.

### Precautions

**PRECAUTIONS INCLUDE INFORMATION REGARDING SPECIAL CARE REQUIRED FOR THE SAFE AND EFFECTIVE USE OF THE DEVICE.**

**General Precautions:**

⚠ **CAUTION:** UNITED STATES LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

⚠ **CAUTION:** PERSONNEL INVOLVED IN THE HANDLING, USE, AND DEACTIVATION OF BRELLA® MUST BE APPROPRIATELY TRAINED.

⚠ **CAUTION:** DO NOT USE IF THE FOIL POUCH IS COMPROMISED (E.G., TEARS, PUNCTURES, OR LOSS OF SEAL).

⚠ **CAUTION:** DO NOT OPEN THE POUCH IF IT IS NOT INTENDED FOR IMMEDIATE USE. MOISTURE AND OXYGEN IN THE AIR MAY CAUSE BRELLA® TO BEGIN RELEASING ENERGY PREMATURELY. DO NOT USE BRELLA® IF THE POUCH HAS BEEN OPENED FOR MORE THAN 30 MINUTES.

⚠ **CAUTION:** DO NOT CUT OR ALTER BRELLA® IN ANY WAY; DOING SO WILL INCREASE THE RISK OF BURNS OR OTHER INJURY.

**Periprocedural Precautions:**

⚠ **CAUTION:** BRELLA® SHOULD NOT BE USED ON ABRADED OR BROKEN SKIN.

⚠ **CAUTION:** DO NOT TREAT IF HAIR LENGTH PREVENTS COMPLETE DRYING OF TREATMENT AREA OR PREVENTS ASSESSMENT OF THE TREATMENT AREA FOR REDNESS OR ABRASIONS.

⚠ **CAUTION:** TREATMENT AREA MUST BE COMPLETELY DRY WHEN BRELLA® IS APPLIED TO TREATMENT SURFACE. IMMEDIATELY REMOVE PATCH IF PATIENT EXPERIENCES PAIN OR AN UNEXPECTED LEVEL OF DISCOMFORT UPON INITIAL PLACEMENT OF BRELLA® AS THIS MAY BE A SIGN OF MOISTURE OR IRRITATED SKIN.

⚠ **CAUTION:** IMMEDIATELY REMOVE BRELLA® IF THE PATIENT REPORTS SIGNIFICANT PAIN RATED 8 OR HIGHER ON A SCALE OF 1-10.

⚠ **CAUTION:** DO NOT LEAVE BRELLA® ON THE AXILLA FOR MORE THAN 3 MINUTES.

⚠ **CAUTION:** AFTER DEACTIVATION, THE DEACTIVATION SOLUTION IS CORROSIVE. IF THE FLUID CONTACTS SKIN, FLUSH WITH SOAP AND WATER.

## Potential Adverse Effects

The following clinical adverse events have been reported during treatment of the axilla for sweat reduction. The risks of these events occurring have been mitigated as much as possible by device design and training.

**Adverse Events (reported during Brella® clinical study)**

- Skin erosion (peeling)
- Redness (erythema) or blotchiness
- Swelling (edema) or bruising
- Bromhidrosis
- Sweating in other parts of the body
- Irritation
- Burning or stinging
- Discomfort or pain
- Discomfort during post-treatment cleaning

**Potential Adverse Events (not reported during Brella® clinical study)**

- Scar or contracture
- Infection
- Numbness or altered sensation
- Skin discoloration
- Blister formation
- Injury to eyes or mouth, if gloves or hands that handled Brella® touch the eyes or mouth
- Allergic reaction to device materials
- Decreased hair growth
- Bumps
- Intolerance of deodorant
- Itching, tightness, or tingling

In addition to the above, there may be adverse events that have not yet been identified.

## Materials

**To minimize risk, set up two separate areas with materials:**

**Brella® Materials**

- Two Brella® Patch packets
- One Brella® deactivation kit

**Miscellaneous Materials**

- Water
- Alcohol
- Gauze
- Timer or clock
- Gloves

Turn Page Over ⟶

## Pre-Treatment Instructions for Patients

**Prior to treatment, provide patients with the following instructions:**

1. **Shave or clip axillae at least 72-hours prior to treatment.**
   **Rationale:** Hair removal is needed because hair prevents complete contact of Brella® to the skin. Shaving, waxing, or clipping hair in the 2 days prior to the procedure may result in small cuts or areas of broken skin. Moisture from broken skin may result in excessive heat production and increased risk of adverse events. Patients who shave, wax, or clip hair in the 2 days prior to treatment cannot receive treatment.
2. **Contact your clinician if there is any redness or discomfort in the treatment area.**
   **Rationale:** Moisture from broken skin may result in excessive heat production and increased risk of adverse events. Patients who have inflamed skin on the day of treatment cannot receive treatment.
3. **Do not use antiperspirant on day of treatment.**
   **Rationale:** Effective treatment requires perspiration to activate the heating of Brella®. Use of products that reduce perspiration may render the treatment less effective or ineffective.
4. **Wear loose fitting clothing (e.g., a tank-top) on day of treatment.**
   **Rationale:** This will allow maximum access to the underarm. Additionally, the underarm area will be rinsed after treatment to remove any residue on the skin. As a result, the surrounding clothing may get wet.

## Prepare Patient for Treatment

### Identify Treatment Area

To identify the treatment area, position the patient comfortably with their arm(s) above their head. A recommended positioning is to have the patient seated with their hands clasped behind their head or resting on a headrest. The patch will be placed centered on the axilla hair follicles.

### Clean Area

Clean the entire treatment area using isopropyl alcohol and gauze pads.

### Confirm Patient Eligibility

Inspect the treatment area. Please refer to the table below for details on treatment area requirements and the course of action to take if requirements are not met.

Both axillae should be examined before proceeding with treatment.

| Requirement | Course of Action if Not Met |
|---|---|
| **Hair-Free:** Hair must be removed (clipped, waxed, or shaved) at least 72-hours prior to treatment.<br><br>Stubble or minimal hair in the treatment area is acceptable. | Do not treat. Have patient return with hair clipped or shaven at least 72-hours prior to treatment. |
| **Clear:** Area must be free from redness, dermatitis, abrasions, broken skin, or other condition of concern.<br><br>Skin tags, moles, and other superficial abnormalities are not a safety concern but may prevent active material of patch from fully contacting the axilla and should be avoided if possible. | Do not treat. Have the patient return when the treatment area is healed or issue has resolved. |
| **Clean:** Area must be free from antiperspirant, deodorant, or other residue. | Clean and dry treatment area with isopropyl alcohol and gauze pads before proceeding. |

⚠ **CAUTION:** DO NOT TREAT PATIENTS WHO HAVE CLIPPED, WAXED, OR SHAVED HAIR IN THE 2 DAYS PRIOR TO THE PROCEDURE.

⚠ **CAUTION:** DO NOT TREAT IF HAIR LENGTH PREVENTS COMPLETE DRYING OF TREATMENT AREA OR PREVENTS ASSESSMENT OF THE TREATMENT AREA FOR REDNESS OR ABRASIONS.

⚠ **CAUTION:** BRELLA® SHOULD NOT BE USED ON ABRADED OR BROKEN SKIN.

⚠ **CAUTION:** STINGING OR BURNING DURING APPLICATION OF ALCOHOL MAY BE AN INDICATION OF COMPROMISED SKIN, WHICH SHOULD NOT BE TREATED.

⚠ **CAUTION:** CARE SHOULD BE TAKEN WHEN TREATING PATIENTS WITH DEEP CREASES IN THE AXILLA, THICKENED/MACERATED OR WET EPIDERMIS, OR PROMINENT PERIFOLLICULAR PAPULES. IN A CLINICAL STUDY, THE PRESENCE OF 2 OUT OF 3 OF THESE FEATURES INCREASED THE RISK OF AN ADVERSE SKIN REACTION. PATIENTS WITH THESE CONDITIONS MAY BE TREATED, BUT REQUIRE ADDITIONAL ATTENTION TO ASSESS PATIENT DISCOMFORT DURING TREATMENT. REMOVE BRELLA® IMMEDIATELY IF PATIENT EXHIBITS SIGNIFICANT DISCOMFORT.

⚠ **CAUTION:** IN A CLINICAL STUDY, SUBJECTS WITH STRIAE IN THE SURROUNDING SKIN WERE AT SLIGHTLY INCREASED RISK OF A SKIN REACTION. PATIENTS WITH THIS CONDITION MAY BE TREATED, BUT REQUIRE ADDITIONAL ATTENTION TO ASSESS PATIENT DISCOMFORT. REMOVE BRELLA® IMMEDIATELY IF PATIENT EXHIBITS SIGNIFICANT DISCOMFORT.

### Encourage Sweating

Sweat must be present to activate Brella®.

## Recommendations for Optimal Treatment

**The effectiveness of the treatment may be impacted if there is not enough sweat present to activate Brella®.** When the active material contacts sweat, thermal energy is produced. This temporarily inactivates sweat glands leading to a reduction in sweat production. The patch must be applied to dry skin but is then activated as the patient sweats. Diminished efficacy may occur if the patient is not actively sweating during treatment.

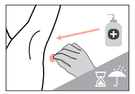
**During treatment, the following steps may be taken to encourage active sweating:**

- Conduct treatment in a warm room (approximately 70-75°F).
- Provide a blanket or other warming device to induce sweating.
- Use hand warmers (provided) in the axilla to induce sweating in the treatment area.
- Suggest physical exertion, such as a brisk walk or other exercise, to induce sweating.
- Consider adjusting the treatment schedule to align with the patient's sweat triggers, such as consuming caffeine or certain foods, or scheduling the treatment during times of the day when sweating is more likely to occur.

If the patient is not sweating, consider rescheduling the treatment.

## Device Use

### Step 1: Prep

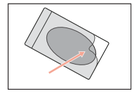


- **Ensure the patient is sweating.**
- **Position the patient with underarm as flat as possible.** Once the patient is sweating, position patient comfortably in a treatment chair, evaluate patient positioning for comfort with treatment area as flat as possible.
- **Dry the treatment area.** Dry the treatment area using clean gauze. Extra effort should be taken to ensure that skin creases and folds are dry as these areas are prone to trapping sweat and moisture.

### Step 2: Apply Patch and Massage

**Treat only one axilla at a time.**

- **Open Brella® packet.** Ensure gloved hands are completely dry. Open one Brella® Patch packet by peeling apart the tabs at end of foil packet, remove Brella® and filter paper, and place both on a clean, flat, and dry surface. Set the foil packet aside.
- **Filter paper** should be kept completely dry on a flat surface in close proximity to the deactivation kit. Never place a patch onto wet filter paper.
- **Remove release liner and apply Brella® patch.** Do not remove the release liner from Brella® until the treatment area is dry and the patient is ready for immediate placement of Brella® on the axilla. Identify release tab at edge of Brella® and carefully remove non-adhesive release liner. Place patch on the axilla. Smooth Brella® to ensure there are no wrinkles or folds, maximizing contact between Brella® and skin. Immediately remove patch if patient experiences pain upon placement of Brella®.



Only the treatment area that comes in contact with the active area of Brella® will be treated. Hair follicles visible outside this area may indicate incomplete treatment coverage.

Areas of skin folds or creases may gather moisture or sweat as these areas prone to pooling of moisture. Take extra care in ensuring that they are dry before placing patch.

⚠ **CAUTION:** TREATMENT AREA MUST BE COMPLETELY DRY WHEN BRELLA® IS APPLIED TO TREATMENT SURFACE. IMMEDIATELY REMOVE PATCH IF PATIENT EXPERIENCES PAIN OR AN UNEXPECTED LEVEL OF DISCOMFORT UPON INITIAL PLACEMENT OF BRELLA® AS THIS MAY BE A SIGN OF MOISTURE OR IRRITATED SKIN.


- **Start timing for 3 minutes.**
- **Gently massage the treatment area.** Throughout treatment, apply gentle pressure to Brella®, continuing to ensure maximum contact between Brella® and skin.
- **Continuously assess patient pain/discomfort.** It is normal and expected for Brella® to get warm as treatment progresses. If at any time the patient reports significant pain rated 8 or higher on a scale of 1-10, promptly remove Brella®.

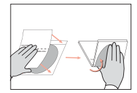
In clinical studies the average pain score reported was 2.4 out of 10, with the average maximum pain was 3.8 out of 10. Thus, it is expected that most patients will NOT experience significant pain during the Brella® procedure. Importantly, there was no correlation between the amount of pain and the effectiveness of the treatment.

### Step 3: Remove and Deactivate Patch

**Deactivate Brella® immediately after removal.** Personnel involved in the handling, use, and deactivation of Brella® must be appropriately trained.

- **Remove patch after 3 minutes.** Remove Brella® after 3 minutes even if the patient is not experiencing any pain or discomfort. Place Brella® to the side with treatment side up.

**DO NOT leave patch on the axilla for more than 3 minutes.** Individual treatment times may vary, but clinical results show no difference in efficacy beyond this time.



- **Cover and fold patch**. Cover patch with filter paper using adhesive to secure filter paper to patch. Fold patch in half on the dotted line with filter paper on the inside of the fold.

⚠ **CAUTION:** DO NOT ALLOW MOISTURE TO CONTACT PATCH OR FILTER PAPER.

- **Place patch in disposal container.** Snap open the lid of one of the disposal containers included in the Brella® deactivation kit. Slide the folded patch into the container. Close the lid of the container, applying pressure until you hear a click. The patch is now undergoing deactivation.

Patch deactivation must occur at room temperature (68-77°F).

- **Put deactivation kit aside.** Refocus attention to the patient.

To prevent leakage, ensure that the deactivation kit is kept upright. During the deactivation process, heat is generated and gas is formed, which may cause the container to feel warm to the touch and produce noises due to bubbling and venting.

⚠ **CAUTION:** AFTER DEACTIVATION, THE SOLUTION IS CORROSIVE. IF THE FLUID CONTACTS SKIN, FLUSH WITH SOAP AND WATER.

**WARNING:** THE ALKALI METAL ON BRELLA® MAY BE FLAMMABLE IF IT CONTACTS WATER, ALCOHOL, OR OTHER WATER-CONTAINING FLUID. PRECAUTIONS SHOULD BE TAKEN TO ENSURE NO WATER CONTACTS THE USED PATCH.

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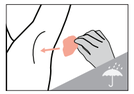
### Step 4: Clean Axilla



- **Wipe axilla with wet gauze.** Using water-soaked gauze, gently wipe treated axilla. Repeat 3-5 times, as necessary, to remove all residue from the treated area. Discard gauze according to facility practices.

The skin on the underarm should not have any residue remaining after cleaning with wet gauze. Continue rinsing if the subject experiences any continued discomfort, or if the skin in the treated area has any visible residue or is slippery when touched with a gloved hand.

⚠ **CAUTION:** IF GLOVE COMES INTO CONTACT WITH THE SODIUM ON BRELLA®, IMMEDIATELY CHANGE GLOVES BEFORE CONTINUING.

### Step 5: Repeat

**Repeats Steps 1-4 on the other axilla. Replace wet gloves with dry ones before handling the second patch for the other axilla.**

### Step 6: Dispose of the Deactivated Patches

- After both patches are in their disposal containers, cover the deactivation kit and move as needed. Set aside for at least 1 hour to ensure complete deactivation, then dispose of the deactivation kit in accordance with federal, state, and local regulations.

**WARNING:** IMPROPER DISPOSAL OF PATCH MAY RESULT IN FIRE.

## Symbols on Device Labeling and Packaging

| | | |
|---|---|---|
| CAUTION | Lot number | WARNING: Corrosive |
| CAUTION: United States law restricts this device to sale by or on the order of a physician | Quantity | WARNING: Flammable material |
| Temperature limits | Catalog number | Do not use if package is damaged |
| Use-by date | Consult instructions for use | Do not re-use, single use device |
| Keep dry | Manufacturer | |

**Manufactured for:**
**Candesant Biomedical, Inc.**
3856 Bay Center Place
Hayward, CA 94545

Candesant® Biomedical