BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

Contents

1.Device Description

Black Touch™ is a sterile, biodegradable, viscoelastic, non-pyrogenic, clear, colorless, and homogenous soft hyaluronic acid gel with moderate lifting capacity. The product contains 17.5 mg/mL of sodium hyaluronate suspended in phosphate-buffered saline at a pH of 7. In addition, *Black Touch™* is formulated with 3 mg/mL lidocaine hydrochloride to enhance patient comfort by reducing pain during the injection procedure.

2.Intended use

Black Touch™ is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21. This product is designed to provide volume and lift to facial areas, enhancing natural contours and softening deep lines for a more youthful appearance.

3.Contraindications

- Severe Allergies: *Black Touch™* is contraindicated in patients with severe allergies, particularly those with a history of anaphylaxis or multiple severe allergies. It should not be used in individuals with known allergies to hyaluronic acid products or lidocaine.
- Bleeding Disorders: *Black Touch™* should not be used in patients with bleeding disorders, as injections may increase the risk of bruising, bleeding, or hematomas at the injection site.
- Lidocaine Hypersensitivity: The product contains lidocaine, and is therefore contraindicated for patients with a known allergy or hypersensitivity to lidocaine or other amide-type local anesthetics.
- Infection or Inflammation at Injection Site: Do not inject *Black Touch™* into areas with active skin infections, inflammation, or rashes (e.g., cysts, pimples, rashes, or hives). Treatment should be postponed until these conditions have completely resolved.

4.Warnings

- Vascular Injection Risks: Injection of *Black Touch™* into blood vessels can lead to serious complications such as embolization, vessel occlusion, ischemia, or infarction. To minimize this risk, practitioners should inject the product slowly and apply minimal pressure. Rare but severe adverse effects, including temporary or permanent vision impairment, blindness, stroke, skin necrosis, or damage to facial structures, have been reported. If any symptoms such as changes in vision, stroke signs, skin blanching, or unusual pain occur during or after the injection, stop immediately and seek prompt medical attention. Immediate evaluation by a healthcare specialist is necessary if intravascular injection is suspected.
- Avoid Use in Vascular-Rich Areas: *Black Touch™* must not be injected into blood vessels or vascular-rich areas. Superficial necrosis and scarring can occur after injection in or near blood vessels due to vessel injury or obstruction. Special care should be taken in patients who have undergone previous surgical procedures in the treatment area.
- Inflammatory Skin Conditions: Use of *Black Touch™* should be deferred in areas where active skin conditions, such as infections, rashes, cysts, or pimples, are present. Postpone treatment until these underlying conditions have fully resolved.
- Previous Surgical Procedures: Patients who have undergone prior surgical interventions in the planned treatment area may be at increased risk of complications. Special caution is advised in such cases, as tissue changes may affect injection outcomes.
- Care with Sensitive Patients: *Black Touch™* should be used cautiously in patients with a predisposition to forming hypertrophic scars, keloids, or those with abnormal wound healing responses, as this can increase the likelihood of scarring.
- Needle/Cannula Handling: Improper attachment of the needle or cannula to the syringe could result in needle disengagement or product leakage. Care should be taken during needle assembly to prevent such occurrences, as it may affect the outcome of the procedure.
- Concurrent Use of Lidocaine: *Black Touch™* contains lidocaine. If additional anesthesia is required (e.g., dental block or topical anesthetic), ensure that combined lidocaine levels do not exceed recommended limits. High doses of lidocaine may cause toxic effects on the central nervous system and cardiac conduction. Practitioners should monitor for signs of

toxicity, especially in patients with epilepsy, cardiac conduction issues, or severe liver/kidney dysfunction.

- Patient Counseling: Practitioners should ensure that patients are well-informed about the potential risks and symptoms of complications, such as vascular occlusion and other adverse reactions. Patients should be educated on the signs of serious complications and instructed to seek immediate medical help if needed.

5.Precautions

- Single Use Only: *Black Touch™* is packaged for single-patient, single-session use only. It must not be resterilized. Do not use if the packaging is opened or damaged.
- Use in Approved Areas Only: The safety and effectiveness of *Black Touch™* for the treatment of areas outside of facial wrinkles and folds have not been established through controlled clinical studies.
- Risk of Infection: As with any transcutaneous procedure, the implantation of dermal fillers carries a risk of infection. Standard precautions typically associated with injectable materials must be observed.
- Product Integrity: *Black Touch™* should be used as supplied. Any modification of the product or its use outside the provided Directions for Use may negatively impact the sterility, homogeneity, and overall performance of the product.
- Pregnancy and Nursing: The safety of *Black Touch™* has not been established for use during pregnancy, in breastfeeding women, or in patients younger than 22 years old.
- Edema Risk: In patients prone to edema (fluid retention or swelling), the use of *Black Touch™* may result in more pronounced discoloration and excessive swelling.
- Superficial Injections: Injecting *Black Touch™* too superficially or in areas with limited soft tissue support (such as areas with thin skin) may lead to contour irregularities or palpable lumps.
- Immunosuppression: The product should be used with caution in patients receiving immunosuppressive therapies, as this could potentially interfere with wound healing or increase the risk of infection.

- Bleeding Disorders: Special caution should be taken when treating patients with known bleeding disorders or those taking medications that may prolong bleeding (e.g., aspirin, nonsteroidal anti-inflammatory drugs, and anticoagulants). These patients may experience increased bruising or bleeding at the treatment sites.
- Post-Procedure Exposure: After treatment with Black Touch™, patients should minimize exposure to excessive sunlight, UV lamps, and extreme temperatures until any initial swelling and redness have subsided.
- Concurrent Treatments: If procedures such as laser treatment, chemical peeling, or other active dermal responses are being considered after treatment with Black Touch™, there is a risk of triggering an inflammatory reaction at the injection site. The same caution applies if *Black Touch™* is used before the skin has completely healed after any such procedures.
- Herpes Reactivation: Injection of *Black Touch™* may potentially cause reactivation of herpes simplex virus in patients with a history of herpetic eruptions.
- Inflammatory Pigmentation: Post-inflammatory pigmentation changes and scarring might occur after dermal filler injections. Patients with abnormal wound healing (e.g., keloids) or those with darker skin tones (Fitzpatrick Types IV-VI) are more prone to develop hypertrophic scarring.
- Handling and Disposal: After use, syringes and needles may be considered potential biohazards. Handle and dispose of these items following accepted medical practices and local, state, and federal requirements.
- Biodegradation Variability: Individual patient variations and the treatment area may affect the degradation rate of Black Touch™. The product may still be detectable in the tissue even after the clinical effect has subsided.
- Product Clarity: *Black Touch™* should be a clear, colorless gel without any particulates. If the contents of a syringe appear separated or cloudy, do not use it.
- Needle Attachment: Improper attachment of the needle may lead to disengagement or product leakage at the connection point between the needle hub and Luer lock.
- Lidocaine Content: *Black Touch™* contains lidocaine. Additional care should be taken when administering this product in conjunction with other amide-type anesthetics. Caution is

advised for patients with epilepsy, impaired cardiac conduction, or severe liver or kidney dysfunction.

6.Postmarketing Surveillance

Following the release of *Black Touch™* into the market, data from both voluntary reporting indicated several commonly observed adverse events. The most frequently reported side effects include transient swelling or edema, either immediately or delayed, up to several weeks post-treatment.

Other less common adverse events reported include:

- Mass formation or induration
- Erythema
- Pain or tenderness
- Papules or nodules
- Bruising or hematoma
- Shortened duration of effect
- Discoloration or hyperpigmentation
- Ischemia or necrosis, typically resulting from unintentional intravascular injection or embolization
- Infection, including bacterial abscess formation
- Injection site reactions, such as burning sensation, discomfort, dryness, exfoliation, irritation, or warmth
- Hypersensitivity or angioedema

Additionally, the following events have been reported:

- Inflammation
- Device displacement or dislocation
- Pruritus (itching)
- Deformity or overcorrection
- Neurological symptoms, including hypoesthesia (numbness) or paresthesia (tingling)

- Eye disorders, such as swelling, blurred vision, and visual impairment
- Granuloma or foreign body reaction
- Rash, blisters, vesicles, atrophy, or scarring
- Acne
- Herpes infection reactivation
- Dermatitis
- Urticaria (hives)
- Capillary disorders, such as telangiectasia
- General symptoms, including chills, dizziness, headache, and malaise

In cases where adverse events occurred, treatments included the use of ice, massage, warm compresses, corticosteroids, antibiotics, antihistamines, analgesics, antiviral agents, and sometimes hyaluronidase to break down the hyaluronic acid filler.

Severe adverse reactions were rare but included ischemia, necrosis, serious eye disorders, and infection or abscess formation. In most cases, patients recovered with appropriate medical intervention, although outcomes varied from resolved to ongoing at the time of last contact.

7.Clinical Studies

A pivotal, multi-center, double-blinded, randomized, active-controlled clinical study was conducted to assess the safety and effectiveness of *Black Touch™* in the treatment of moderate to severe nasolabial folds. The study used a split-face design, where subjects were randomized to receive *Black Touch™* on either the right or left side of the face, with a comparator product injected on the opposite side.

The clinical protocol allowed for up to two initial treatment sessions spaced approximately three weeks apart (comprising the initial injection and a touch-up). After 48 weeks, subjects were eligible for up to two retreatment sessions (again spaced three weeks apart if needed).

All subjects attended regular follow-up visits at 3, 12, 24, 36, and 48 weeks post-injection to assess the treatment's safety and effectiveness. The primary effectiveness variable was the improvement

in wrinkle severity from baseline, as evaluated using the Wrinkle Severity Rating Scale (WSRS), a validated 5-point scale. Secondary endpoints included subject self-assessments of wrinkle severity using a 5-point scale and pain levels using an 11-point Numeric Pain Intensity Scale (NPIS).

Effectiveness Results

The primary endpoint of the study was met, with subjects experiencing a statistically significant improvement in nasolabial fold appearance. After six months, 78.8% of the subjects treated with *Black Touch™* exhibited a one-point or more improvement on the WSRS. By the 12-month mark, 62.3% of the treated areas maintained the improvement.

Subjects reported high satisfaction with the treatment, with 78.8% at six months and 66.7% at one year indicating noticeable improvement. Across all time points, *Black Touch™* was shown to provide long-lasting, effective wrinkle reduction.

8.Instruction for use

A. Attaching the Needle to the Syringe

1. While wearing surgical gloves, carefully remove the cap from the needle and unscrew the tip cap from the syringe.
2. Hold the syringe barrel firmly and grasp the needle shield with the other hand.
3. Attach the needle securely to the syringe by simultaneously pushing and rotating it firmly until the needle is completely locked into place. Ensure there is minimal space between the needle shield and the syringe to confirm proper assembly.
4. Remove the needle shield immediately before injection by pulling it straight out—do not rotate.

   Note: Improper assembly may result in leakage or disconnection of the needle.

B. Instructions for Healthcare Professionals

1. *Black Touch™* is a cross-linked hyaluronic acid gel, specifically designed for facial contouring and volumizing, injected using a 30 G needle. It is effective in treating facial wrinkles and folds.
2. Prior to treatment, the patient's medical history should be reviewed, and they should be fully informed of the indications, contraindications, warnings, precautions, and potential adverse reactions associated with Black Touch™. Pre-treatment photographs are recommended to document the baseline condition, and patients should be advised that "touch-up" treatments may be necessary to achieve and maintain optimal correction.
3. Although *Black Touch™* contains lidocaine for pain relief, additional anesthesia may be used to enhance comfort during and after the injection, depending on the patient's needs.
4. Ensure that the treatment area has been thoroughly washed with soap and water. Prepare the skin with alcohol or another appropriate antiseptic before injection.
5. Needle Safety: To avoid breakage, do not bend or manipulate the needle before or during treatment. If the needle becomes bent, discard it and replace it with a new one. Do not attempt to reshield used needles; discard them immediately in approved sharps collectors.
6. Before injecting, press the plunger carefully until a small droplet of *Black Touch™* is visible at the tip of the needle.
7. Blocked Needle: If the needle becomes blocked, do not increase pressure on the plunger. Instead, stop the injection and replace the needle. If resistance is encountered, partially or fully withdraw the needle, check for function, and replace if necessary.
8. After needle insertion, and just before the injection, slightly withdraw the plunger rod to aspirate and confirm that the needle is not in a blood vessel.
9. Once the initial small amount of product is injected, wait a few seconds to allow the lidocaine to take effect before continuing the procedure.

10. The injection technique, depth, and volume should be tailored to the patient's treatment needs. A combination of retrograde linear threading and serial puncture techniques can be employed. Injecting the product too superficially may result in visible lumps or bluish discoloration. It is advisable to change the needle for each new treatment site.
11. Injecting Technique: Administer *Black Touch™* by applying even pressure to the plunger rod while slowly withdrawing the needle. Stop the injection just before the needle is fully removed from the skin to prevent leakage or superficial placement of the filler.
12. Injection Volume: The typical injection volume required to achieve optimal correction of moderate to severe nasolabial folds is approximately 1.5 mL per treatment site. For retreatments, a volume of about 1.0 mL per site is usually sufficient.
13. Correct the treated area to 100% of the desired volume but avoid overcorrection.
14. If blanching (whitening of the skin) occurs during the injection, stop immediately and massage the area until normal color returns. Blanching may indicate vessel occlusion. If normal skin color does not return, discontinue the injection and treat according to the American Society for Dermatologic Surgery guidelines, which may include hyaluronidase injection.
15. After the injection, gently massage the treated area to mold the product and ensure even distribution. If overcorrection occurs, massage the area between your fingers or against a bony surface to achieve optimal results.
16. For patients with localized swelling, it may be difficult to judge the degree of correction during the initial treatment. In these cases, a follow-up touch-up session may be required to achieve the desired outcome.
17. Patients may experience localized treatment site reactions, which typically resolve within 1 to 2 weeks. If swelling persists immediately after injection, an ice pack wrapped in a protective cloth can be applied to reduce swelling and discomfort.

Exercise caution when applying ice to areas still numb from anesthetic to avoid thermal injury.

18. Instruct the patient to report any issues related to the treatment or adverse reactions following the procedure with Black Touch™.

C. Patient Instructions

Patients should be provided with the following post-treatment guidelines:

- For the first 24 hours after treatment, patients should avoid strenuous exercise, excessive sun exposure, and heat. These factors may exacerbate temporary redness, swelling, and itching at the treatment sites.
- If swelling occurs, an ice pack may be applied for short periods to the treated area to reduce discomfort.
- Patients should promptly report any adverse reactions or concerns to their healthcare provider.

9.Post-Treatment Care

After treatment with Black Touch™, patients may experience localized swelling, redness, tenderness, or bruising at the injection site. These symptoms are typically mild to moderate and usually resolve within 1 to 2 weeks following the procedure. To enhance comfort and support recovery, the following post-treatment care guidelines are recommended:

1. Ice Application: If the treated area is swollen or sore, an ice pack wrapped in a protective cloth may be gently applied for short periods. Use caution to avoid direct contact with the skin, especially if the area is still numb from the anesthetic, to prevent thermal injury.
2. Avoid Strenuous Activity: Patients should avoid strenuous exercise, sunbathing, or exposing the treated area to extreme heat or UV light for the first 24 hours after the procedure. Such activities may increase swelling, redness, or discomfort.

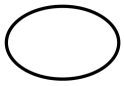
3. Touch-Up Treatments: Depending on the patient's individual response and the degree of correction achieved, a follow-up appointment may be necessary for touch-up treatments. This helps ensure optimal and long-lasting results.
4. Skin Care: Patients should be instructed to keep the treated area clean and avoid applying excessive pressure or massaging the area unless directed by the healthcare provider.
5. Reporting Adverse Reactions: It is important to inform patients to promptly report any unusual symptoms or adverse reactions to their healthcare provider. Any persistent pain, significant swelling, or signs of infection should be evaluated immediately.
6. Duration of Effects: The aesthetic results of *Black Touch™* typically last several months, depending on the individual's skin type, area treated, and lifestyle factors. Follow-up treatments may be scheduled to maintain or enhance the results.

10. Storage and Handling

- Store at room temperature up to 25°C .
- Do not freeze the product or expose it to excessive heat or direct sunlight.
- Do not use the product if the packaging is damaged or if the expiration date has passed.
- Each syringe is for single use only and must be discarded immediately after use.
- To place an order, contact Pol Tech Central Office: 021-284208

11. Glossary Symbols

Symbol	Symbol Title	Explanatory Text
	Manufacturer	Indicates the medical device manufacturer
	Use-by date	Indicates the date after which the medical device is not to be used.
	Lot code	Indicates the manufacturer’s batch code so that the batch or lot can be identified.

REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Consult instructions for use	Indicates that important information regarding safety, usage, and precautions is contained in the documentation, and this information should be reviewed before using the product.
	Sterilized using steam	Indicates a medical device that has been sterilized using steam.
	Single sterile barrier system	Indicates a single sterile barrier system. The packaging system for a sterile medical device is composed of one or more sterile barriers.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Temperature limit	indicates the recommended storage temperature range for a medical device or product.

Manufactured by:

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