

**Table of Contents**

1. Glossary .....	2
2. Product Description .....	2
3. Effectiveness .....	3
4. Clinical Study .....	4
5. Safety .....	8
6. Risks .....	9
7. When should I call my doctor? .....	10
8. Injection and Administration .....	10
9. What if I experience a problem? .....	11

## 1. Glossary

The glossary section defines important terms to help you understand the product and the treatment process:

- Anesthetic: Used to numb the area and minimize pain during the procedure.
- Cannula: A blunt-tipped tube that can be used instead of a needle for smoother, less painful injections, particularly for cheek or midface treatments.
- Hyaluronic Acid (HA): A naturally occurring substance in your body that keeps skin hydrated, plump, and elastic. In *Black Design™*, the HA is modified to last longer in the skin.
- Hyaluronidase: An enzyme that can break down HA if needed, for example, if a correction is required.
- Lidocaine: A local anesthetic included in *Black Design™* to reduce discomfort during the procedure.
- NSAID: Nonsteroidal anti-inflammatory drugs (like ibuprofen) that reduce inflammation and pain.
- Touch-up: A follow-up injection of a small amount of product to fine-tune the results, typically administered two weeks after the initial treatment if necessary.
- BDDE: A chemical used to crosslink HA, which helps the filler stay in place longer.

## 2. Product Description

What is *Black Design™* with Lidocaine?

*Black Design™ with Lidocaine* is a hyaluronic acid-based filler designed to Design volume, smooth wrinkles, and contour the face or hands. It is crosslinked with BDDE, making it last longer in the body than naturally occurring HA. The product also contains 0.3% lidocaine to make the procedure more comfortable.

How does *Black Design™* with Lidocaine work?

When injected into the skin, *Black Design™* adds volume to smooth out lines and wrinkles, such as the nasolabial folds (lines running from the nose to the mouth corners). It can also be used to enhance cheek fullness and treat volume loss in the hands. Depending on the area, injections are made with an ultrafine needle or a blunt cannula to reduce discomfort and bruising.

Why is lidocaine included in *Black Design™*?

Lidocaine helps minimize pain during and after the injection. In studies, patients who received *Black Design™ with Lidocaine* reported significantly less pain compared to those treated without lidocaine. Pain relief from lidocaine can last up to an hour post-treatment.

How long does *Black Design™* last?

- **Wrinkles and folds:** When used for lines and wrinkles, *Black Design™* lasts about 6 months as the filler gradually dissolves.
- **Cheek fullness:** Results in the cheeks can last from 2 to 12 months.
- **Hand volume:** For hand treatments, the benefits typically last around 6 months.

### 3. Effectiveness

*What were the outcomes in clinical trials?*

Clinical trials demonstrated that *Black Design™* is effective for various cosmetic purposes. Key findings include:

- **Wrinkles and folds:** In trials involving patients treated for nasolabial folds (the lines from the nose to the mouth), participants reported significant improvements in wrinkle depth and skin smoothness, with results lasting for 6 months.
- **Cheek fullness:** In a study of 200 patients, significant improvements in cheek contour were reported, with results lasting between 2 to 12 months.

- **Hand volume:** Another study of 89 patients showed improvements in hand volume, with effects lasting around 6 months.

In these trials, both patients and doctors evaluated the results at various intervals (2, 4, 6, 8, 10, and 12 months), confirming that *Black Design™* provided long-lasting and consistent improvement.

#### 4. Clinical Study

*Black Design™* underwent comprehensive clinical trials to evaluate its safety and effectiveness in three key areas: facial wrinkles and folds (specifically nasolabial folds), cheek volume restoration, and hand volume rejuvenation. These trials involved hundreds of participants and were designed to ensure that *Black Design™* met the highest standards of safety and efficacy for aesthetic treatments.

- **Wrinkles and Folds (Nasolabial Folds)**

The primary focus of these clinical studies was to test the effectiveness of *Black Design™* in reducing the appearance of **nasolabial folds** (the deep lines that run from the sides of the nose to the corners of the mouth). Over **509 patients** participated in multiple randomized, controlled clinical trials.

- **Study Design:**

- The participants were randomly assigned to receive either *Black Design™* or no treatment.
- Both doctors and patients assessed the changes in the appearance of nasolabial folds over several months.
- The evaluation periods included 2, 4, 6, and 12 months after the initial treatment, providing a long-term view of the product's effectiveness.

- **Results:**

- Patients who received *Black Design™* injections experienced a significant improvement in the depth and visibility of their nasolabial folds compared to those who did not receive treatment.

- The effects lasted for up to 6 months, after which the filler gradually broke down and was absorbed by the body.
- Blinded evaluators (doctors who were unaware of whether a patient received treatment or not) confirmed these results, ensuring that the assessment was unbiased.
- **Patient Experience:**
  - Most patients reported smoother and more youthful skin in the areas treated with *Black Design™*.
  - Improvements were typically noticeable within weeks of the injection, and the effect was maintained throughout the 6-month study period.
  - No major complications were reported in relation to the treatment of nasolabial folds, making *Black Design™* a reliable choice for this purpose.
- **Cheek Volume and Contouring**

In addition to wrinkle reduction, *Black Design™* was studied for its ability to Design volume to the cheeks and improve facial contour. This is particularly important for patients experiencing age-related volume loss in the mid-face, which can result in a sagging or hollow appearance.

- **Study Design:**
  - A total of **200 patients** participated in this study.
  - Some patients received injections with a traditional needle, while others were treated with a **cannula**, a blunt-tipped device that can reduce the risk of bruising and swelling.
  - The study included evaluations at intervals of 2, 4, 6, 8, 10, and 12 months, allowing for a comprehensive analysis of the product's longevity.
- **Key Findings:**
  - Patients reported **significant improvements** in the fullness and contour of their cheeks.

- The results lasted between **2 and 12 months**, depending on the individual's response to the filler.
- In particular, patients who were treated with a **cannula** experienced fewer side effects such as bruising and swelling, which are common with needle injections. This makes cannula injections a preferred option for those looking to minimize recovery time.
- **Impact on Appearance:**
  - Patients reported a noticeable improvement in facial lift and volume, contributing to a more youthful and rejuvenated appearance.
  - The filler not only added volume but also improved the overall contour and shape of the face, helping to restore the natural facial structure that diminishes with age.
- **Hand Volume Restoration**

As people age, they often experience volume loss in the hands, which can make veins and tendons more prominent and give the hands an aged appearance. *Black Design™* was tested in a clinical trial involving **89 patients** to address this issue.

- **Study Design:**
  - The study focused on treating the back of the hands with *Black Design™* to restore lost volume and smooth out the skin.
  - Patients were evaluated at multiple points, including the 6-month mark, to determine how long the effects lasted.
- **Results:**
  - Patients reported **visible improvements** in hand volume and a more youthful appearance within weeks of treatment.
  - The results typically lasted for about **6 months**, after which the filler gradually began to dissipate.
  - In this study, **two methods** were used: traditional needle injections and injections using a **cannula**. The cannula method resulted in fewer side effects but was

associated with a slightly higher risk of complications, such as reduced thumb flexibility.

- **Patient Satisfaction:**

- Most patients were satisfied with the results, noting smoother, fuller hands and a reduction in the appearance of prominent veins and tendons.
- The treatment helped restore a youthful look to the hands without the need for invasive procedures.

- **Lidocaine Study for Pain Reduction**

Lidocaine, a local anesthetic, is included in *Black Design™* to reduce pain and discomfort during and after the injection. To test the effectiveness of lidocaine, a split-face study was conducted with 60 patients.

- **Study Design:**

- Each patient received *Black Design™* without lidocaine on one side of their face and *Black Design™* with lidocaine on the other side.
- Patients were asked to rate their pain on a scale from 0 to 100.

- **Results:**

- On the side treated without lidocaine, patients rated their pain as 47 on average.
- On the side treated with *Black Design™* containing lidocaine, patients rated their pain as 15, indicating a significant reduction in discomfort.
- Pain relief from the lidocaine lasted up to 60 minutes after the injection, providing continued comfort during the immediate post-treatment period.

- **Patient Comfort:**

- This study confirmed that the inclusion of lidocaine in *Black Design™* makes the procedure much more comfortable for patients, reducing the need for additional pain management measures.
- The anesthetic effect also helps reduce anxiety for patients who may be concerned about discomfort during the treatment.

- **Blinded Evaluations and Safety**

To ensure the accuracy and reliability of the results, all clinical studies used blinded evaluations. This means that the doctors assessing the patients' results did not know which patients had received *Black Design™* and which had not. This method eliminates bias and ensures an objective assessment of the product's effectiveness.

- **Safety Profile:**

The clinical trials confirmed that *Black Design™* has a favorable safety profile:

- Common side effects, such as bruising, swelling, and tenderness at the injection site, were mild and resolved within a week or two.
- Rare but more serious complications, such as infection or vascular events, were carefully monitored. In cases where these complications arose, they were effectively managed with appropriate medical interventions, such as antibiotics or hyaluronidase (an enzyme used to dissolve the filler).

## **Conclusion of Clinical Studies**

The clinical studies conducted on *Black Design™* clearly demonstrated its effectiveness in treating facial wrinkles, enhancing cheek volume, and restoring hand volume. The results were long-lasting, and the inclusion of lidocaine significantly reduced pain and discomfort for patients during and after the procedure. Overall, *Black Design™* proved to be a safe and reliable dermal filler for achieving a more youthful and rejuvenated appearance in both the face and hands.

## **5.Safety**

*Are there any reasons I shouldn't use Black Design™?*

Certain conditions make *Black Design™* unsuitable for some patients:

- **Severe allergies:** If you have a history of severe allergic reactions (anaphylaxis), using *Black Design™* may trigger another allergic response.



- **Allergies to lidocaine or HA proteins:** If you are allergic to lidocaine or the bacterial proteins used to produce the HA in *Black Design™*, it's not safe to use.
- **Bleeding disorders:** If you have a condition that makes you prone to bleeding or bruising, you may have a higher risk of complications.

### Precautions

Your doctor will review your medical history before administering *Black Design™*. Be sure to discuss:

- **Treatment areas:** *Black Design™* is intended for use around the nose, mouth, cheeks, and hands. It's not recommended for other areas of the face.
- **Skin conditions:** Postpone treatment if you have active skin sores, rashes, or infections. Using the filler in these areas could delay healing or worsen the condition.
- **Age considerations:** The product has not been studied in patients younger than 18 for wrinkles or in those younger than 22 for cheek and hand treatments. Similarly, its safety has not been studied in individuals over 65 for wrinkles.
- **Pregnancy and breastfeeding:** Safety has not been established for pregnant or breastfeeding women.
- **Immunosuppressive therapy:** If you are on medications that suppress the immune system, you may have an increased risk of infection.
- **Blood-thinning medications:** Inform your doctor if you are taking blood thinners (like aspirin or warfarin), as these can increase the risk of bruising and bleeding at the injection site.

## 6.Risks

You may experience the following side effects after treatment with *Black Design™*:

- **Common side effects:** Bruising, redness, swelling, tenderness, and small bumps at the injection site. These typically resolve within 1-2 weeks.
- **Delayed reactions:** In some cases, people have experienced delayed reactions (up to 138 days after treatment) including redness, bruising, and inflammation.

- **Infection:** There is a small risk of infection at the injection site, which can be treated with antibiotics.
- **Scarring:** Although rare, there is a risk of scarring at the injection site.
- **Hyperpigmentation:** Patients with darker skin tones may experience temporary darkening of the skin at the treated site, which usually resolves within a few weeks.
- **Cold Sores:** If you have a history of cold sores, facial injections may trigger a recurrence.

## 7. When should I call my doctor?

Contact your doctor immediately if you experience:

- **Vision changes:** Blurred or distorted vision can be a sign of unintentional injection into a blood vessel, which can lead to serious complications.
- **Signs of a stroke:** Symptoms include difficulty speaking, weakness or numbness in your face, arms, or legs, confusion, dizziness, or severe headache.
- **White appearance of the skin:** This could indicate poor blood flow due to unintentional injection into a blood vessel, which could result in tissue damage.
- **Unusual pain:** Severe pain during or after the procedure could be a sign of an underlying issue, such as infection or vascular complications.

## 8. Injection and Administration

### What should I do before treatment?

Before receiving *Black Design™*, follow these guidelines:

- **Avoid blood-thinning agents:** One week before your treatment, avoid medications and supplements like St. John's Wort, NSAIDs (such as aspirin and ibuprofen), and high doses of vitamin E, as they can increase the risk of bruising.
- **Facial cold sores:** If you've had cold sores in the past, inform your doctor. They may prescribe medication to minimize the chance of recurrence.

## Aftercare

To minimize side effects and ensure the best results, follow these post-treatment steps:

- **Cold compresses:** Apply a clean, cold compress to the treated area immediately after the procedure to reduce swelling.
- **Avoid touching:** Do not touch or rub the treated area for at least 6 hours. After this time, gently wash the area with soap and water.
- **Limit sun exposure:** Avoid exposing the treated area to intense sunlight or tanning beds until any redness or swelling has subsided.
- **Avoid certain medications:** For one week after treatment, avoid aspirin, NSAIDs, St. John's Wort, and vitamin E supplements to reduce the risk of bruising.

## 9.What if I experience a problem?

If you believe that you have experienced a serious problem related to *Pol Tech* products, you should contact your doctor immediately. If you have any questions regarding *Pol Tech* products, you can personally reach out to our customer support team. Our representatives are available to assist you between 8:00 a.m. and 5:00 p.m. (local time), Saturday through Thursday.

Please contact us at:021-284208