

# Patient Consent for Clinical Intake and Treatment

StudioMeds, PLLC

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This document is the consent you provide to StudioMeds, PLLC for the clinical intake and the treatment that the prescribing physician may authorize as a result. Please read it in full before proceeding. If you have questions, contact [admin@studiomed.com](mailto:admin@studiomed.com) before proceeding.

## Section 1. The service you are consenting to

You are completing a clinical intake questionnaire so that a Michigan-licensed physician can determine whether it is medically appropriate for you to use a specific over-the-counter topical anesthetic during your tattoo or permanent makeup procedure.

The physician's role is limited. The physician evaluates your eligibility for the topical anesthetic and, if you are eligible, issues a written prescription authorizing your use of the anesthetic during the procedure. The physician does not perform your procedure. The procedure itself is performed by a separately licensed body art facility and its hired professionals.

Approval is not guaranteed. The physician will review your intake responses and your identity verification documents and will issue the prescription only if it is medically appropriate to do so. You will not be charged if you are determined not to be medically appropriate.

You confirm that all information you provide in the intake questionnaire is true, accurate, and complete to the best of your knowledge. The physician relies on your responses to determine whether the prescription is appropriate. Inaccurate or incomplete information may increase your risk of harm and may invalidate the physician's approval.

## Section 2. The medications that may be prescribed

Depending on your intake responses and the procedure you are seeking, the physician may prescribe one of the following over-the-counter topical anesthetic products. All three products are FDA-regulated over-the-counter topical anesthetics:

### For tattoo procedures and brow permanent makeup:

- Aspercreme 4% Lidocaine, for application to intact skin before the procedure.

- Bactine Max Spray, containing lidocaine and benzalkonium chloride, for application during the procedure to provide ongoing analgesia and antimicrobial coverage at the wound site.

**For lip blush and permanent eyeliner procedures:**

- Zensa Numbing Cream (5% lidocaine), for application before the procedure to the lip area or to the periocular skin at the lash line and pretarsal area, respectively.

The physician's prescription will specify which product is authorized for your procedure and will include specific instructions for use, including the maximum amount that may be applied. Use of the product outside these instructions, including by you or by the artist performing your procedure, may result in harm.

**Section 3. Off-label use**

All three over-the-counter topical anesthetic products that StudioMeds may prescribe (Aspercreme 4% Lidocaine, Bactine Max Spray, and Zensa Numbing Cream) are prescribed off-label, meaning they are prescribed for a use that is not specifically reflected in the manufacturer's FDA-approved labeling. The off-label dimension differs by product:

For Aspercreme 4% Lidocaine and Bactine Max Spray the off-label dimension is the use of the product for pre-procedure or in-procedure anesthesia in the context of body art, which is not the specific use reflected in the manufacturer's labeling.

For Zensa Numbing Cream, prescribed for lip blush and permanent eyeliner procedures, the off-label dimension is the anatomical site of application (lip vermilion and vermilion border for lip blush; periocular skin at the lash line and pretarsal area for permanent eyeliner).

Off-label use of FDA-regulated medications by a licensed physician based on clinical judgment is a recognized and lawful element of medical practice. The physician's decision to prescribe each of these products reflects the active ingredient's well-established pharmacology, the formulation's suitability for the intended use, and widespread use of these or similar formulations in the body art and permanent makeup industries. The full clinical reasoning supporting each product recommendation is documented in the StudioMeds Clinical Rationale for Recommended Topical Anesthetic Products, available on request.

You acknowledge that the off-label nature of the prescription means there is less FDA-reviewed safety data specific to the body art use than would exist for an on-label use, and that you have the opportunity to discuss off-label medication use with the prescribing physician before proceeding if you have questions or concerns.

**Section 4. Risks common to all StudioMeds prescriptions**

The following risks apply to all topical anesthetic products that StudioMeds may prescribe.

**Allergic and hypersensitivity reactions.** You may develop an allergic reaction to the active ingredient (lidocaine) or to other ingredients in the prescribed product. Reactions can range from local irritation, redness, and swelling at the application site to, in rare cases, severe whole-body reactions including widespread hives, breathing difficulty, throat tightness, or anaphylaxis. If you develop signs of a serious reaction at any point, stop using the product and seek immediate medical care.

**Local anesthetic systemic toxicity (LAST).** When too much topical anesthetic is absorbed into the bloodstream, it can affect the heart, brain, and other organs. Risk of LAST is reduced when the prescription is used as directed, including the maximum dose limit specified in your prescription. Risk increases substantially when more than the prescribed amount is applied, when the product is applied for longer than directed, when the product is applied to broken or compromised skin not specifically authorized by the prescription, when multiple anesthetic products are used together, or when the product is occluded under wraps or coverings not specifically authorized by the prescription.

Early signs of LAST include numbness around the mouth, metallic taste, ringing in the ears, lightheadedness, and visual disturbance. More severe signs include muscle twitching, seizure, irregular heartbeat, and loss of consciousness. If you experience any of these symptoms during or after the procedure, immediately inform the artist performing your procedure, stop the procedure, and seek emergency care if symptoms are severe or progressive. Call 911 for any severe or rapidly progressive symptoms.

**Patient responsibility for proper use.** You accept responsibility for following all usage instructions in your prescription. You also accept responsibility for ensuring that any artist or technician who applies the medication on your behalf does so only within the prescribed instructions. You understand that use is optional and that you may proceed with your procedure without the prescribed anesthetic.

## **Section 5. Procedure-specific risks: tattoo and brow permanent makeup**

In addition to the risks in Section 4, the following risks apply when the prescribed product is used during a tattoo procedure or brow permanent makeup procedure.

**Application during the procedure on broken skin.** When Bactine Max is applied during the procedure as authorized by the prescription, the skin is intentionally broken. Topical anesthetic absorbed through broken skin reaches the bloodstream more rapidly than through intact skin. Risk of LAST is increased relative to application on intact skin and is the reason the prescription specifies a maximum amount that may be applied during the procedure.

**Skin irritation, contact reaction, or infection at the procedure site.** Both Aspercreme and Bactine Max can cause local irritation or contact reaction at the application site. Bactine Max contains an antimicrobial agent (benzalkonium chloride) that helps reduce the risk of procedural contamination but does not eliminate the general risk of infection associated with any procedure that breaks the skin.

This consent does not address risks of the tattoo or permanent makeup procedure itself, including but not limited to infection, scarring, pigment migration, dissatisfaction with aesthetic result, need for touch-ups, or allergic reaction to pigment. Those risks are addressed in the consent provided by the artist performing your procedure.

## **Section 6. Procedure-specific risks: lip blush**

In addition to the risks in Section 4, the following risks apply when the prescribed product (Zensa Numbing Cream) is used for a lip blush procedure.

**Elevated absorption through lip tissue.** Lip skin is thinner and more vascular than skin elsewhere on the body. Topical lidocaine applied to the lip area is absorbed into the bloodstream more rapidly and more completely than the same product applied to thicker skin. During the procedure, when the artist creates controlled disruption of the lip surface to deposit pigment, absorption increases further.

If you experience early signs of LAST as described in Section 4 during your procedure, immediately inform the artist. The artist will stop the procedure and seek emergency care if warranted.

**Reactivation of cold sores (herpes simplex virus).** People who have ever had cold sores on or around the lips can experience a cold sore outbreak after a lip blush procedure, even if their last outbreak was years ago. This is caused by the trauma of the procedure itself, not the numbing cream, but it is a relevant risk to understand before proceeding. A cold sore outbreak in the days following the procedure can affect healing and the final appearance of the work. People without any known history of cold sores can also experience a first outbreak after a lip procedure.

If you have a history of cold sores, consult your primary care physician about antiviral prophylaxis (such as valacyclovir or acyclovir) before your procedure. Antiviral prophylaxis substantially reduces but does not eliminate the risk of post-procedure outbreak.

**Lip-specific allergic and hypersensitivity reactions.** Lip tissue can react to topical preparations even when the same product has been used on other body areas without difficulty. Local reactions at the lip can include burning, swelling, blistering, or rash and may affect the healing and final appearance of the procedure. Stop using the product and seek medical care if you develop a severe local reaction or any signs of a generalized reaction.

**Avoiding ingestion.** Apply the product as directed, follow the artist's removal protocol before procedural work begins on the lips, and avoid swallowing residual product. Accidental ingestion of small amounts of residual product is generally not harmful but should be reported to a poison control center if a meaningful amount is ingested.

## **Section 7. Procedure-specific risks: permanent eyeliner**

In addition to the risks in Section 4, the following risks apply when the prescribed product (Zensa Numbing Cream) is used for a permanent eyeliner procedure.

**Migration of product into the eye.** The procedure involves application of the product to the eyelid skin in close proximity to the eye itself. The prescription is for application to the lash line and pretarsal skin only and explicitly does not authorize application to the waterline or mucosal margin of the eye. Despite these protocol limits, migration of small amounts of product into the eye is possible during application, dwell time, or the procedure.

If the product reaches the eye, you may experience burning, redness, blurred vision, or temporary loss of the protective blinking reflex. In most cases this resolves with prompt rinsing with sterile saline (which the artist is required to have available at the workstation). Keep your eyes closed throughout pre-procedure application and dwell time. Immediately report any burning, vision change, eye pain, or other ocular symptoms to the artist. If symptoms persist after rinsing, you should be evaluated by an ophthalmologist or emergency department the same day.

**Contact lens interaction.** If you wear contact lenses, contact lenses can trap migrated product against the surface of the eye and worsen any exposure. Patients who cannot temporarily discontinue contact lens wear for the procedure are not eligible for the prescription.

**Eyelid skin reactions.** Eyelid skin is among the thinnest and most permeable on the body, which can make it particularly sensitive to topical agents. A reaction localized to the eyelid can cause swelling that affects the procedure outcome and can extend to involve the eye itself in rare cases. Stop using the product and seek medical care if you develop a severe local reaction.

## **Section 8. Affiliate relationships disclosure**

The prescribing physician may recommend specific over-the-counter products for use during your procedure and may provide affiliate links to retailers (including the StudioMeds Amazon storefront) where you can purchase the recommended products. If you purchase a recommended product through an affiliate link, StudioMeds may receive a commission from the retailer. This commission does not affect the price you pay.

The clinical recommendation of any product is made solely on the basis of the prescribing physician's clinical judgment and is independent of any commission structure. The full clinical reasoning supporting product recommendations is documented in the StudioMeds Clinical Rationale for Recommended Topical Anesthetic Products, available on request.

Your prescription is complete and valid regardless of where you purchase the recommended product. You may obtain the recommended product from any retailer of your choice. Purchasing from a recommended source is a convenience and is not required.

## **Section 9. Acknowledgment**

When you indicate your agreement on the StudioMeds intake page, you confirm:

- You have read and understand this consent in full.
- You have had the opportunity to ask questions and to discuss off-label medication use with the prescribing physician if you wished to do so.
- You understand that approval for the prescription is not guaranteed and that you will not be charged if you are determined not to be appropriate.
- You understand the risks described in Section 4 and the procedure-specific risks in Sections 5, 6, or 7 that apply to your procedure.
- You accept responsibility for using the prescribed product as directed and for ensuring that any artist applying the product on your behalf does so within the prescribed instructions.
- You understand the affiliate relationships disclosure in Section 8 and that your prescription is complete regardless of where you purchase the recommended product.
- You voluntarily consent to the clinical evaluation and to the treatment described.

Your acknowledgment, the version of this document you acknowledged, the procedure category you selected at intake, and the timestamp of your acknowledgment are recorded in the StudioMeds system.