Clinical Policies and Procedures

Purpose
To ensure safe and effective treatment of patients undergoing Injectable Filler/Restylane administration at a SpaMedica® medspa franchise or corporate store, the following policies and procedures have been developed.

Policy
A Registered Nurse [RN], or Physician Assistant with current state licensure shall be able to assess, consult and treat clients with Injectable Fillers/Restylane following the guidelines set herein. In the state of California, the medical director or a physician assistant must perform a good faith examination prior to the use of Injectable Fillers/Restylane.

(i) Setting
The Registered Nurse [RN], or Physician Assistant can perform the administration of Injectable Fillers/Restylane in various settings and locations, such as but not limited to:

- All Injectable Fillers/Restylane procedures must only be performed within the designated SpaMedica® medspa location that is registered with the Franchisor. All safety policies and procedures, as set out in the SpaMedica® Policy and Procedure manual, must be strictly adhered to.

All Injectable Fillers/Restylane administration procedures shall be performed in a clean, safe environment, equipped with proper sharps disposal system, and universal precautions in place.

(ii) Supervision
The Registered Nurse [RN] or Physician Assistant shall function under the general supervision of the Medical Director who is immediately available for consultation by telecommunication and is physically available as medically necessary. The Medical Director is under contract with the SpaMedica® Medical group, which is a physician-owned company that hires doctors to act on behalf of SpaMedica® for an approved franchise. The SpaMedica® medical spa Franchisor will seek out potential SpaMedica® medical directors for the best medical care and medical supervision with a medspa facility.

Side effects may appear either at the time of treatment or shortly thereafter. Adverse reaction(s) shall be documented in the client’s SpaMedica® treatment record and the chart. All adverse reactions such as bruising, asymmetry, corrections, lumpiness, and patient dissatisfaction shall be reported immediately to the Medical Director. Adverse reaction(s) shall be documented in the client’s SpaMedica® chart.
(iii) Patient Conditions

The Registered Nurse [RN], or Physician Assistant will not knowingly treat any clients with:

1. Allergies to hyaluronic acids,
2. Any clients with significant autoimmune or neurological diseases, or
3. Pregnant clients.

The Registered Nurse [RN], or Physician Assistant will only treat patients with Injectable Fillers/Restylane after completing the SpaMedica® comprehensive Franchisee clinical training program and reviewed the sections in the clinical services manual dealing with the use of Injectable Fillers/Restylane in the face and will not treat any portion outside of the face and those areas specified in the SpaMedica® clinical services manual.

Injectable Fillers/Restylane Procedure

The Registered Nurse [RN], or Physician Assistant will:

1. Complete the SpaMedica® assessment and a medical history questionnaire with all new clients.
2. Clients with a history of allergies to human albumin, clients with significant neurological and autoimmune diseases, or pregnant clients will be denied treatment.
3. Upon passing medical screening, clients will be fully informed of risks, benefits, and potential adverse reactions and a SpaMedica® informed consent will be signed.
4. Injectable Filler/Restylane shall be stored in a cool cupboard, ready for use.
5. Remove the Restylane from its sterile wrapped package and place the enclosed luhr lock needle on the syringe. Perform the injection in a sterile and effective fashion, as outlined in the SpaMedica® clinical services training manual.
6. Clients are injected while in a seated position.
7. Clients are asked to demonstrate dynamically the function of the muscle groups to be injected, as some clients may require both Injectable Filler/Restylane and Botox® to achieve the desired goals.
8. The specific techniques of injection are outlined in the SpaMedica® clinical services training manual.
9. After each injection the skin may be massaged moderately and pressure held with a gauze. It is important to massage the Restylane thoroughly into the soft tissue when you have completed the injection.

10. When procedure is completed the client should massage the product for 10 minutes twice daily for two days.

11. The amount of Restylane, specific injections techniques, end points and maintenance are outlined in our work Franchisee training manual.

(iv) Record Keeping

The Registered Nurse [RN], or Physician Assistant shall be responsible for maintaining client SpaMedica® Injectable Filler/Restylane treatment records, including but not limited to client assessment, signed informed consent of risks, benefits, and potential adverse effects, number of treatments, treatment sites, number of injections, solution/concentration used, and the client response to treatment. The injectable facial drawing should be completed.

Requirements for Clinical Personnel

(v) Training / Education

The Registered Nurse [RN], or Physician Assistant must complete the SpaMedica® franchisee certification and clinical training program. The SpaMedica® Medical Director, either a Medical Doctor, Doctor of Osteopathy, must also have completed the franchisee certification course. Competencies to successfully demonstrate shall include:

- Mechanism of Action of Injectable filler/Restylane
- Basic Theory of Treatment for Cosmetic Purposes
- Facial Anatomy
- Natural History of the Injectable Fillers
- Safety, efficacy, and complication issues
- Assessment and identification of areas to be treated
- Safe application of injection techniques [minimum 8 hours hands on training]
- Complications and their management
(v) **Competencies & Documentation**

The Medical Director and RN or PA shall:

- Keep on the wall of a treatment room in the SpaMedica® franchise facility the certificate of completion of the SpaMedica® franchise clinical services training program.

- Keep on the wall or on file in the franchise facility the most current of the yearly re-certification SpaMedica® clinical services certificates. The Franchisor will perform the re-certification for each of the franchisee procedures on a yearly basis.

- The Yearly SpaMedica® re-certification shall be maintained in the personnel file of the Registered Nurse [RN], Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

- Document [on the appropriate form] the initial evaluation and final determination recording satisfactory completion of training and competence.

- Evaluate the competence of the Registered Nurse [RN], Physician Assistant or licensed medical personnel on an annual basis and/or as needed if indicated by client dissatisfaction or efficacy issues.

- The evaluation shall be maintained in the personnel file of the Registered Nurse, Physician Assistant or licensed medical personnel at the appropriate administrative office [employing facility].

**Development and Approval of Standardized Procedure**

The SpaMedica® Clinical Policies and Procedures for the Administration of Injectable Filler/Restylane have been developed jointly by the Medical Director, Administrator, Advanced Practice Nurse and/or Registered Nurse. This procedure shall be reviewed on an annual basis and documentation pertinent to that review shall be kept on file in the designated administrative office.

Signatures of authorized personnel approving the standardized procedure:

<table>
<thead>
<tr>
<th>Nurse</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Director</td>
<td>Date</td>
</tr>
<tr>
<td>Administrator</td>
<td>Date</td>
</tr>
</tbody>
</table>
### Personnel Authorized to Perform Procedure

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Injectable Post Treatment Instructions

- Facial exercise in the area of treatment is recommended [frown/smile 1 hour].
- Avoid manipulation of the area for the first four hours after procedure.
- Subsequent massage of the product as outlined above is recommended.

**Note:** These measures should minimize the possibility of ptosis.

- Treatment effect may take 3–8 days to appear.
- The benefits may last 3–6 months; the average is 4 months.
- A touch-up may be necessary in 1–2 weeks for any unevenness or asymmetry.
- Contact the practitioner as soon as possible after the eighth [8th] day if you have not achieved the desired effect.
RESTYLANE INSTRUCTIONS FOR USE

Formula

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyaluronic acid, stabilized</td>
<td>20 mg/ml</td>
</tr>
<tr>
<td>Phys. sodium chloride solution, pH 7</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

Description

RESTYLANE is a clear, transparent and viscous gel supplied in a glass syringe together with a 30 G needle. The product is for single use only.

RESTYLANE is a unique form of non-animal, stabilized hyaluronic acid (NASHA). Hyaluronic acid is a natural polysaccharide which occurs as an important structural element in the skin and in subcutaneous and connective tissues as well as in the synovial fluid and blood. Hyaluronic acid belongs to a group of very few substances which are identical in all living organisms.

Mode of action

RESTYLANE acts by adding volume to the tissue, thereby restoring the skin contours or enhancing the lips to the desired level of correction. RESTYLANE injection is naturally integrated into the tissue and will in time undergo isovolumetric degradation.

Indication and usage

RESTYLANE is intended to be used for facial tissue augmentation. It is recommended that the product be used for the correction of wrinkles and for lip enhancement. It should be injected into the middle part of the dermis layer of the facial skin. With excessive contour deformities, the best results are obtained if the defect can be manually repositioned to the point where it is eliminated. The degree and duration of the correction depend on the character of the defect treated, the tissue area at the implant site, the depth of the implant in the tissue, and the injection technique. Markedly inflammatory defects may be difficult to correct. For the correction of thin superficial lines, RESTYLANE Fine Lines is recommended. For lip enhancement both RESTYLANE and PERLANE can be used. For shaping, the contours of the face and for the correction of folds, PERLANE is recommended. Also combinations of RESTYLANE, PERLANE and RESTYLANE Fine Lines can be used. Please consult the PERLANE and the RESTYLANE Fine Lines In instructions for more information.

Warning

RESTYLANE is only intended for use as an intradermal implant. Do not re-use RESTYLANE. Do not inject intravenously. Do not mix with other products.

Precautions

Normal precautions associated with intradermal injections must be observed. Like any such procedure, the implantation of RESTYLANE is associated with an inherent risk of infection. RESTYLANE should not be used in or near anatomical sites where there is active skin disease, inflammation or related conditions. Do not use RESTYLANE together with any other injectable implant, except for PERLANE Fine Lines and PERLANE. RESTYLANE should not be injected into an area where a permanent implant has been placed. RESTYLANE should not be used for patients with unsuitable expectations. The patient should be informed that he or she should not expose the treated area to adverse heat (e.g. sunlight and sunbathing) or extreme cold at least until the initial swelling and redness have resolved. If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with RESTYLANE, there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if RESTYLANE is administered before the skin's healing condition after such a procedure. There is a potential risk with the procedure that the material could be inadvertently injected into dermal blood vessels, which could lead to permanent scarring in an embarrassing or corresponding consequences. No such cases have been reported to date with RESTYLANE. RESTYLANE has not been tested in pregnant or lactating women or in children.

Anticipated side-effects

After the injection of RESTYLANE, some common injection-related reactions might occur. These reactions include erythema, swelling, pain, itching, discoloration or tenderness at the implant site. Typically, reaction is spontaneous within a few days after injection into the skin and within a week after injection into the lips. Additionally, temporary palpable lumpiness has been noted after the use of RESTYLANE in some patients.

The composition of RESTYLANE is a set to balance a normal tissue pressure. However, because the tissue pressure is sometimes disrupted to a higher value such as during cosmesis or to a lower value such as during dehydration, a small but significant change (swelling or shrinking) may occur.

Adverse events

Reactions thought to be of a hypersensitivity nature have been reported in about 1 in every 2,000 treatments. These consist of swelling and inflammation at the implant site, sometimes with edema in the surrounding tissues. Erythema, tenderness and rarely, a subcutaneous papule may also occur. The reactions have started either shortly after injection or after a delay of 1-2 weeks and have generally been described as mild to moderate and with some limited with an average duration of 2 weeks. In pronounced cases a short course of oral corticosteroids may prove effective. In addition, rare cases (less than 1 in 15,000 treatments) of granuloma formation, superficial necrosis and arthritis have been reported. Patients who have experienced this type of reaction should not be retreated with Q-Med Esthetic products.

Adverse events must be reported to the local Q-Med representative.

Interactions

Treatment with RESTYLANE in combination with other drugs and devices has not been tested.

Assembly of needle to syringe

For safe use of RESTYLANE it is important that the needle is properly assembled. See pictures A and B.

A. Unscrew the tip cap of the syringe carefully.

B. 1. Take a loose grip on the narrow part of the needle shield and mount the needle on the needle by screwing until you feel some counterpressure.

B. 2. Take a new fine grip on the wider part of the needle shield.

B. 3. Pull off the needle shield.

Dosage and administration

Before the treatment, the patient's suitability for the treatment and the need for pain relief should be assessed. Normally, no anaesthesia is necessary when creating wrinkles. For lip augmentation, anaesthesia through a nerve block can be used. The patient should be informed about the indications, expected results, contraindications, precautions, warnings, and potential adverse events. The treatment site should be cleaned with a suitable antiseptic solution. RESTYLANE is administered using a thin gauge needle (30 G) by injecting the material into the dermis. If RESTYLANE is injected too deep or intramuscularly, the duration of the implant will be shorter because of a higher hyaluronic acid turnover rate. An injection too superficial may give bleaching effects and bumps on the treatment site. If bleaching is observed, i.e. the injected skin turns a whitish colour, the injection should be stopped at once and the area massaged until it returns to a normal colour. Before injecting, press the rod carefully until a small droplet is visible at the tip of the needle.

The injection technique with regard to the depth of injection and the administered quantity may vary. The linear threading technique can be used to carefully lift up the wrinkles, but some physicians prefer a series of punctual injections or a combination of the two. During injection, it is recommended that the eye of the needle should face upwards. The contour of the needle should be visible but not the colour of the needle. Inject RESTYLANE while pulling the needle slowly backwards. Injection should stop just before the needle is pulled out from the skin to prevent material from leaking out from the injection site. In the treatment of lips, an elevated vermilion border as well as fullness and peeling can be obtained. Please consult your local Q-Med representative for details. Defocus should be fully corrected, but not overcorrected, at each treatment session. If the skin of the patient is very loose, it is recommended that RESTYLANE be injected on two separate occasions. The connection site should be massaged to conform to the contour of the surrounding tissues. For each treatment site a maximum dosage of 2 ml per treatment session is recommended. If the treated area is swollen directly after the injection, melting ice can be applied on the site for a short period. After the first treatment, additional implications of RESTYLANE may be necessary to achieve the desired level of correction. Periodic follow-up injections help sustain the desired degree of correction.
Note! The correct injection technique is crucial for the final result of the treatment. RESTYLANE is only intended to be administered by authorized personnel in accordance with local legislation.

The syringe, the needle and any unused material must be discarded directly after the treatment session.

New supplied
RESTYLANE is supplied in a glass syringe with a luer lock fitting. A sterile irradiation sterilized needle, 30 G x 1/2", is packed together with each syringe of RESTYLANE. A patient record label is a part of the syringe label (see picture C). Remove it by pulling the flap marked with three small arrows (see picture D). This label is to be attached to patient records to ensure traceability of the product. The contents of the syringe are sterile. The number of units per package and the volume contained in each syringe are stated on the outer package.

PROCEDURE PACK CE-MARKED PRODUCT:
STERILE NEEDLE, 1 x 30 G x 1/2"
- Follow national, local or institutional guidelines for use and disposal of medical sharp devices. Obtain prompt medical attention if injury occurs.
- To help avoid needle breakage, do not attempt to straighten a bent needle. Discard it and complete the procedure with a replacement needle.
- Do not restick used needles. Recapping by hand is a hazardous practice and should be avoided.
- Discard unshielded needles in approved sharps collectors.

Shelf life and storage
As indicated on package. Store at a temperature of 2 - 25°C. Protect from sunlight and freezing.

Manufactured by
Q-Med AB, Simmungsgraten 21, SE-752 28 Uppsala, Sweden
Phone +46(0)18 474 90 00, Fax +46(0)18 474 90 01
http://www.q-med.com, e-mail info@q-med.com

IF THE PACKAGE IS DAMAGED, DO NOT USE

Symbols on packaging:
⚠️ Refer to instructions for use

For single use.

°C ±5°C

LOT

Use until date

STERIL

STERIL. The products are sterilized according to European Standards.

STERILE

STERILE. The contents of the syringe have been sterilized by using moist heat.

CE

STERILE. The needle has been sterilized by using irradiation.

CE-marked according to MDD 93/42 EEC.

ISO 11134 is No of notified body

References
Up-to-date product documentation is available at Q-Med in Sweden, at your local retailer or on http://www.q-medesthetics.com.

* RESTYLANE, RESTYLANE Fine Lines and PERLANE are trademarks owned by Q-Med AB.
Summary of Instructions for Use

Restylane® Instructions for Use

Formula
Contents:
- Hyaluronic acid, stabilized: 20 mg/ml
- Phys. sodium chloride solution: pH 7 q.s.

Description
RESTYLANE® is a clear, transparent and viscous gel supplied in a glass syringe together with a 30 G needle. The product is for single use only. RESTYLANE® is a unique form of non-animal, stabilized hyaluronic acid (NASHA). Hyaluronic acid is a natural polysaccharide which occurs as an important structural element in the skin and in subcutaneous and connective tissues as well as in the synovial tissue and fluid. Hyaluronic acid belongs to a group of very few substances that have an identical form in all living organisms. Therefore, hyaluronic acid in its pure form is highly biocompatible.

Mode of action
RESTYLANE® acts by adding volume to the tissue, thereby restoring the skin contours or enhancing the lips to the desired level of correction. The implant is naturally integrated into the tissue and will in time undergo isovolemic degradation.

Indication and usage
RESTYLANE® is intended to be used for facial tissue augmentation. It is recommended that the product be used for the correction of wrinkles and for lip enhancement. It should be injected into the middle part of the dermis layer of the facial skin. With cutaneous contour deformities the best results are obtained if the defect can be manually stretched to the point where it is eliminated. The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue and the injection technique. Markedly indurated defects may be difficult to correct. For the correction of thin superficial lines RESTYLANE® Fine Lines is recommended. PERLANE® is recommended for shaping the contours of the face, for the correction of folds and for lip enhancement. Please consult the PERLANE and the RESTYLANE Fine Lines Instructions for Use for more information.

Warning
RESTYLANE is only intended for use as an intradermal implant. Do not resterilize RESTYLANE. Do not inject intravascularly. Do not mix with other products.
Precautions

Normal precautions associated with intradermal injections must be observed. Like any such procedure, the implantation of RESTYLANE is associated with an inherent risk of infection. RESTYLANE should not be used in or near anatomic sites where there is active skin disease, inflammation or related conditions. Do not use RESTYLANE together with any other injectable implant, except for RESTYLANE Fine Lines and PERLANE. RESTYLANE should not be injected into an area where a permanent implant has been placed. RESTYLANE should not be used for patients with unattainable expectations.

The patient should be informed that he or she should not expose the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold at least until the initial swelling and redness have resolved.

If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with RESTYLANE there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if RESTYLANE is administered before the skin has healed completely after such a procedure.

Anticipated side-effects

After the injection of RESTYLANE, some common injection-related reactions might occur. These reactions include erythema, swelling, pain, itching, discoloration or tenderness at the implant site. Typically, resolution is spontaneous within one to two days after injection into the skin and within a week after injection into the lips. Additionally, temporary palpable lumpiness has been noted after the use of RESTYLANE in some patients. The composition of RESTYLANE is set to balance a normal tissue pressure. However, because the tissue pressure is sometimes disturbed to a higher value such as during oedema or to a lower value such as during low water intake, a small but significant change (swelling or shrinkage) may occur.

Adverse events

Reactions thought to be of a hypersensitivity nature have been reported in about one in every 2,000 treated patients. These have consisted of swelling and induration at the implant site, sometimes with oedema in the surrounding tissues. Erythema, tenderness and rarely acneform papules may also occur. The reactions have started either shortly after injection or after a delay of 2–4 weeks and have been described as mild to moderate and self-limiting, with an average duration of 2 weeks. In pronounced cases a short course of oral corticosteroids may prove effective. Patients who have experienced this type of reaction should not be retreated with RESTYLANE.

There is a potential risk with the procedure that the material could be inadvertently injected into dermal blood vessels, which could lead to vascular occlusion in an end-artery with corresponding consequences. No such cases have been reported to date with RESTYLANE. Adverse events must be reported to the local Q-MED representative.
**Interactions**

Treatment with RESTYLANE in combination with other drugs and devices or during pregnancy or lactation has not been tested for.

**Assembly of needle to syringe**

For safe use of RESTYLANE it is important that the needle is properly assembled. 1. Take a loose grip on the narrow part of the needle shield and mount the needle on the luer-lock by screwing until you feel some counterpressure. 2. Take a new firm grip on the wider part of the needle shield and turn it a further 90° (a quarter of a turn). 3. Pull off the needle shield.

**Dosage and administration**

Before the treatment, the patient’s suitability for the treatment and the need for pain relief should be assessed. Normally, no anaesthesia is necessary when treating wrinkles. For lip augmentation, anaesthesia through a nerve block can be used. The patient should be informed about the indications, expected result, contraindications, precautions, warnings and potential adverse events. The treatment site should be cleaned with a suitable antiseptic solution. RESTYLANE is administered using a thin gauge needle (30 G) by injecting the material into the dermis. If RESTYLANE is injected too deep or intramuscularly, the duration of the implant will be shorter because of a higher hyaluronic acid turnover rate. Too superficial an injection may give blanching effects and bumps on the treatment site. Before injecting, press the rod carefully until a small droplet is visible on top of the needle.

The injection technique with regard to the depth of injection and the administered quantity may vary. The linear threading technique can be used to carefully lift up the wrinkle, but some physicians prefer a series of punctual injections or a combination of the two. During injection it is recommended that the eye of the needle should face upwards. The contour of the needle should be visible but not the colour of it. Inject RESTYLANE while pulling the needle slowly backwards. Injection should stop just before the needle is pulled out from the skin to prevent material from leaking out from the injection site. In the treatment of lips, an enhanced vermilion border as well as fullness and pouting can be obtained. Please consult your local Q-MED representative for details. Defects should be fully corrected, but not overcorrected, at each treatment session. If the skin of the patient is very loose, it is recommended that RESTYLANE be injected on two separate occasions. The correction site should be massaged to conform to the contour of the surrounding tissues. For each treatment site a maximum dosage of about 1.4 ml is recommended. If the treated area is swollen directly after the injection, melting ice can be applied on the site for a short period. After the first treatment, additional implantations of RESTYLANE may be necessary to achieve the desired level of correction. Periodic touch-up injections help sustain the desired degree of correction.

**Note!** The correct injection technique is crucial for the final result of the treatment. RESTYLANE is only intended to be administered by authorized personnel in accordance with local legislation.
The syringe, the needle and any unused material must be discarded directly after the treatment session.

How supplied
RESTYLANE is supplied in a glass syringe with a luer-lock fitting. A gamma irradiation sterilized needle, 30 G x 1/2", is packed together with each syringe of RESTYLANE. A patient record label is a part of the syringe label. Remove it by pulling the flap marked with three small arrows. This label is to be attached to patient records to ensure traceability of the product. Each syringe contains stabilized hyaluronic acid gel which has been terminally sterilized. The number of units per package and the volume contained in each syringe is as stated on the outer package.

Procedure Pack CE-Marked Product:
STERILE NEEDLE, 1 x 30 G x 1/2"

- Follow national, local or institutional guidelines for use and disposal of medical sharp devices. Obtain prompt medical attention if injury occurs.
- To help avoid needle breakage, do not attempt to straighten a bent needle. Discard it and complete the procedure with a replacement needle.
- Do not reshield used needles. Recapping by hand is a hazardous practice and should be avoided.
- Discard unshielded needles in approved sharps collectors.

Shelf life and storage
As indicated on package. Store at a temperature of 2–25 °C. Protect from sunlight and freezing.

Manufactured by
Q-MED AB, Seminariegatan 21, SE-752 28 Uppsala, Sweden
Phone +46 (0) 18 474 90 00, Fax +46 (0) 18 474 90 01
http://www.q-med.com e-mail: info@q-med.com

IF THE PACKAGE IS DAMAGED, DO NOT USE

References
Up-to-date material concerning the following:
- Safety file
- Clinical file
- Bibliography file
  is available at Q-MED in Sweden or at your local retailer.

* RESTYLANCE, RESTYLANCE Fine Lines and PERLANE are trademarks owned by Q-MED AB.
Perlane® Instructions for Use

Formula
Contents:
Hyaluronic acid, stabilized 20 mg/ml
Phys. sodium chloride solution, pH 7 q.s.

Description
Perlane® is a clear, transparent and viscous fluid supplied in a glass syringe together with a
27 G needle. The product is for single use only. PERLANE is a unique form of non-animal,
stabilized hyaluronic acid (NASHA). Hyaluronic acid is a natural polysaccharide which occurs as
an important structural element in the skin and in subcutaneous and connective tissues as well as
in the synovial tissue and fluid. Hyaluronic acid belongs to a group of very few substances that
have an identical form in all living organisms. Therefore, hyaluronic acid in its pure form is
highly biocompatible.

Mode of action
Perlane® acts by adding volume to the tissue, thereby shaping the contours of the face,
correcting folds or enhancing the lips to the desired level of correction. PERLANE is naturally
integrated into the tissue and will in time undergo isovolemic degradation.

Indication and usage
Perlane® is intended to be used for facial tissue augmentation. It is recommended that the
product be used for shaping the contours of the face, the correction of folds and for lip
enhancement. It should be injected into the deep layer of the dermis and/or the surface layer
of the subcutis. With contour deformities the best results are obtained if the defect can be
manually stretched to the point where it is eliminated. The degree and duration of the correction
depend on the character of the defect treated, the tissue stress at the implant site, the depth of
the implant in the tissue and the injection technique. Markedly indurated defects and very
deep or very superficial wrinkles may be difficult to correct. For the correction of cutaneous
contour deformities such as wrinkles and folds and for lip enhancement it is recommended that
RESTYLANE® is used. RESTYLANE® Fine Lines is recommended for the correction of thin
superficial lines and wrinkles. Also combinations of Perlane, Restylane and Restylane
Fine Lines can be used. It is not advised that PERLANE be used together with any other
injectable implant. Please consult the RESTYLANE and RESTYLANE Fine Lines Instructions
for Use for more information.

Warning
PERLANE is only intended for use as an intradermal and/or subcutaneous implant. Do not
sterilize PERLANE. Do not inject intravascularly. Do not mix with other products, except for
RESTYLANE and RESTYLANE Fine Lines.
**Precautions**

Normal precautions associated with intradermal and/or subcutaneous injections must be observed. Like any such procedure, the implantation of PERLANE is associated with an inherent risk of infection. PERLANE should not be used in or near anatomic sites where there is active skin disease, inflammation or related conditions. PERLANE should not be injected into an area where a permanent implant has been placed. PERLANE should not be used for patients with unattainable expectations.

The patient should be informed that he or she should not expose the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold at least until the initial swelling and redness have resolved.

If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with PERLANE there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if PERLANE is administered before the skin has healed completely after such a procedure.

**Anticipated adverse events**

After the injection of PERLANE, some common injection related reactions might occur. These reactions include erythema, swelling, pain, itching, discoloration or tenderness at the implant site. Typically resolution is spontaneous within one to two days after injection into the skin and within a week after injection into the lips. Additionally, temporary palpable lumpiness has been noted after the use of PERLANE in some patients. The composition of PERLANE is set to balance a normal tissue pressure. However, because the tissue pressure is sometimes disturbed to a higher value such as during oedema or to a lower value such as during low water intake, a small but significant change (swelling or shrinkage) may occur.

**Adverse events**

Reactions thought to be of a hypersensitivity nature have been reported in about one in every 2,000 treated patients. These have consisted of swelling and induration at the implant site, sometimes with oedema in the surrounding tissues. Erythema, tenderness and rarely acneform papules may also occur. The reactions have started either shortly after injection or after a delay of 2–4 weeks and have been described as mild to moderate and self-limiting, with an average duration of 2 weeks. In pronounced cases a short course of oral steroids may prove effective. Patients who have experienced this type of reaction should not be retreated with PERLANE or RESTYLANE.

There is a potential risk with the procedure that the material could be inadvertently injected into blood vessels, which could lead to vascular occlusion in an end-artery with corresponding consequences. Another potential risk could be the damaging of facial nerves. No such cases have been reported to date with PERLANE or RESTYLANE. Adverse events must be reported to the local Q-MED representative.
Interactions
Treatment with PERLANE or RESTYLANE in combination with other drugs and devices or during pregnancy or lactation has not been tested for.

Assembly of needle
For safe and undisturbed use of PERLANE it is important that the needle is properly assembled. 1. Take a loose grip on the narrow part of the needle shield and mount the needle on the luer-lock by screwing until you feel some counterpressure. 2. Take a new firm grip on the wider part of the needle shield and turn it a further 90° (a quarter of a turn). 3. Pull off the needle shield.

Dosage and administration
Before the treatment, the patient’s suitability for the treatment and the need for pain relief should be assessed. Normally, no anaesthesia is necessary when shaping the contours of the face and correcting folds. For lip augmentation, anaesthesia through a nerve block can be used. The patient should be informed about the indications, expected result, contraindications, precautions, warnings and potential adverse events. The treatment site should be cleaned with a suitable antiseptic solution. PERLANE is administered using a thin gauge needle (up to 27 G) by injecting the material into the deep layer of the dermis and/or the surface layer of the subcutis. If PERLANE is injected too deep or intramuscularly, the duration of the implant will be shorter because of a higher hyaluronic acid turnover rate. Too superficial an injection may give blanching effects and bumps on the treatment site. Before injecting, press the rod carefully until a small droplet is visible on top of the needle.

The injection technique with regard to the depth of injection and the administered quantity may vary. PERLANE should only be injected by practitioners who have experience of deep dermal and subcutaneous injections in the facial area. The linear threading technique can be used, but some physicians prefer a series of punctual injections or a combination of the two.

During injection it is recommended that the eye of the needle should face upwards. Inject PERLANE while pulling the needle slowly backwards. Injection should stop just before the needle is pulled out from the skin to prevent material from leaking out from the injection site. In the treatment of lips, fullness and pouting of the lips can be obtained. Please consult your local Q-MED representative for details. Defects should be fully corrected, but not overcorrected, at each treatment session. If the skin of the patient is very loose, it is recommended that PERLANE be injected on two separate occasions. The correction site should be massaged to conform to the contour of the surrounding tissues. For each treatment site a maximum dosage of 1 syringe is recommended. If the treated area is swollen directly after the injection, melting ice can be applied to the site for a short period. After the first treatment, additional implantations of PERLANE may be necessary to achieve the desired level of correction, but this should be done only after a minimum of 4 weeks. Periodic touch-up injections help sustain the desired degree of correction.

Note! The correct injection technique is crucial for the final result of the treatment. PERLANE is only intended to be administered by authorized personnel in accordance with local legislation.
The syringe, the needle and any unused material must be discarded directly after the treatment session.

How supplied
PERLANE is supplied in a glass syringe with a luer-lock fitting. A gamma irradiation sterilized needle, 27 G x 1/2", is packed together with each syringe of PERLANE. A patient record label is a part of the syringe label. Remove it by pulling the flap marked with three small arrows. This label is to be attached to patient records to ensure traceability of the product. Each syringe contains stabilized hyaluronic acid gel which has been terminally sterilized. The number of units per package and the volume contained in each syringe is as stated on the outer package.

Procedure Pack CE-Marked Product:
STERILE NEEDLE, 1 x 27 G x 1/2"

- Follow national, local or institutional guidelines for use and disposal of medical sharp devices. Obtain prompt medical attention if injury occurs.
- To help avoid needle breakage, do not attempt to straighten a bent needle. Discard it and complete the procedure with a replacement needle.
- Do not reshield used needles. Recapping by hand is a hazardous practice and should be avoided.
- Discard unshielded needles in approved sharps collectors.

Shelf life and storage
As indicated on package. Store at a temperature of 2–25 °C. Protect from sunlight and freezing.

Manufactured by
Q-MED AB, Seminariegatan al, SE-752 28 Uppsala, Sweden
Phone +46 (0) 18 474 90 00, Fax +46 (0) 18 474 90 01
http://www.q-med.com e-mail: info@q-med.com

IF THE PACKAGE IS DAMAGED, DO NOT USE

References
Up-to-date material concerning the following:
- Safety file
- Clinical file
- Bibliography file
  is available at your local Q-MED representative or at Q-MED in Sweden.

* PERLANE®, RESTYLANE® Fine Lines and RESTYLANE® are registered trademarks of Q-MED AB.
Consultation Process

Injectable Fillers

1. Client must complete a Medical/Surgical History, review and sign Payment Policy, review and initial pages of Facial Injectable Consent Form. A good candidate for injectable fillers would be between the ages of 25–65. Clients over 65 may be good candidates for surgery instead.

2. Review history with client in consultation. Consent is reviewed as well until client has no further questions.

3. Explain indications for filler such as glabellar lines after Botox®, nasolabial folds, labiomental folds and marionette lines. A good candidate, as stated above, should have had a thorough discussion about product description, risks, benefits, post care and longevity of product (which is up to 6 months). This is also a good time to discuss all other services that SpaMedica® offers. Information pages are available on all procedures.

4. Be sure client is aware of post treatment swelling and bruising, and that they have a post care page to take home with them. It includes the clinic phone number on the bottom of the page if they have any concerns.

5. Discuss all issues regarding injection technique so the client is aware of our Num It cream and the possibility of an injection of xylocaine for freezing the lips. Be sure client has no allergies. Remember cryo cooler is also available.

6. All pages of consent must be initialed, the last page to be filled out by injectable nurse as to specific area of injection. Have client sign the bottom of this page and the nurse will witness with her signature.

7. Photos are taken with the Polaroid camera, usually kept in treatment room one. Photos are labeled and kept in the patient’s chart in envelopes that will stick in the front of the chart. These are kept at the front desk.

In this time of rapidly expanding medical knowledge and the increasing specialization associated therewith, there exists a very real risk of the specialist physician not being aware of the general health and medical background of the patient. On occasion such information may critically affect what procedures we may safely undertake on you and under what circumstances. We therefore ask that you give us the following medical information.

Age: ______ Height: ______ Weight: ______ Occupation: ________________________________

Please list all medications which you are currently taking or have used in the past 6 months (be sure to include any of the following: birth control pills, aspirin or ibuprofen containing drugs, Phen-Fen, Redux, diabetic medications, steroids, glaucoma drops, asthma medications, Digoxin, Lanoxin, nitroglycerin, Isordil, Inderal, other heart medications, Lasix, other diuretics, high blood pressure medications, Coumadin, Persantine, tranquilizers, sleeping pills, anti-depressants, pain pills or injections, epilepsy medications). Use back of page if necessary.

<table>
<thead>
<tr>
<th>Medication(s):</th>
<th>Amount</th>
<th>Frequency</th>
</tr>
</thead>
</table>

Please list all Naturopathic or Health Food Supplements:

List all drug and/or latex allergies:

Have you ever used (circle): LSD/speed/cocaine/marijuana?

If yes, when did you last use ________________________________

Are you a smoker? YES/NO _____ Ex-Smoker YES/NO _____ Non-Smoker YES/NO ______

How much are (were) you smoking? _______ How long? _______ Quit how long ago? _______

How much alcohol do you drink? ___________________________ Caffeine? __________

______________________________
Please circle all of the following medical conditions you now have or have had in the past:
bleeding tendency / diabetes / blood transfusions / glaucoma / dry eyes / lung disease /
TB / asthma or wheezing / emphysema / bronchitis / irregular heart beat / chest pain /
heart disease / high blood pressure / heart attack / stroke / epilepsy / heart burn / intestinal
ulcers or bleeding / rheumatoid arthritis / scleroderma / lupus / depression / mental illness /
drug or alcohol addiction / hepatitis B / hepatitis C / HIV / any other serious illness or injury /
None of the above

Is there any possibility that you may be pregnant at this time? YES/NO _____________________

Do you have a history of herpes simplex (cold sores)? _________________________________

When was the last outbreak? _________________________________________________________

Do you have a history of developing keloids? __________________________________________

Have you ever been on accutane? _______________ When? _______________________________

List all surgeries that you have had (include plastic surgery): Date:

Have you or anyone in your family ever had unusual reactions to anesthesia (muscle weakness,
jaundice, breathing problems or unexpected fever(s)? YES/NO __________________________

Do you have (circle): loose or chipped teeth/caps/dentures/contact lenses/None

Have you ever seen a cardiologist? YES/NO Physician Name: ____________________________

Date of last EKG: __________________________________________________________________

I acknowledge that I have disclosed my complete medical history and the above is a complete and
accurate representation of my medical and psychological status.

Patient Signature: ______________________________________ Date: ________________________
Authorization for Examination and Treatment

Name: _______________________________ Birthdate (mm/dd/yy): _______

Address: _______________________________ City: _______________________

Province: _______ Postal Code: _______ Home Phone: _________________

Work Phone: ___________________________ Referred by: __________________

Health Card No. (& version code) _______________________________________

Emergency Contact Name & Number: ______________________________________

I, _________________________________, represent to the physicians and staff that I am at least 18 (eighteen) years of age or, if not, am accompanied by a legal guardian. I hereby consent to and authorize a history examination by my doctor and such assistant or staff as may be assigned by him/her.

If appropriate, I authorize the release of any medical information for the purpose of processing insurance claims on my behalf. I authorize payments of medical benefits directly to the doctor for services provided to me. A copy of this authorization shall be considered as valid as the original. I understand that photography is a necessary part of planning and evaluating cosmetic procedures. I authorize the taking of photographs at the direction of my physician or physician delegate and under such conditions as may be approved by him/her. These photographs will be used solely for documentation purposes and will be kept confidential unless otherwise disclosed.

I understand that there is a consultation fee for the initial visit which is due at the time of my appointment unless other arrangements have been made in advance.

SIGNATURE: _________________________________ DATE: _____________

RELATIONSHIP: (circle one) PATIENT SPOUSE PARENT GUARDIAN
Payment Policy for Injectables Procedures

A VISA or MasterCard number, cash or certified cheque are required to reserve your appointment time.

Charges will not be applied to your credit card until you arrive for your treatment.

48 business hours are required for cancellation of your appointment to avoid being charged for your treatment.

If you cancel your appointment in less than 48 business hours, or fail to appear for your treatment, a charge of $100.00 will be applied to your credit card.

Although we will do our best to accommodate you, if you are late for your appointment, you may be required to rebook for another day. If this is necessary, the $100.00 fee will be waived.

** Please note that quotes and deposits are valid for 6 months **

Client signature

Date
Facial Injectables (Hyaluronic Acid, Collagen)

Informed-Consent Booklet

Instructions
This is an informed-consent document that has been prepared by Dr. Mulholland to help inform you concerning Facial Injectables (Hyaluronic Acid, Collagen,), their risks, and alternative treatment. During your consultation, Dr. Mulholland, or our SpaMedica® Nurse Injectors will have reviewed the potential benefits of facial injectables, the alternatives and all the risks outlined in this booklet. During the consent discussion process, they will have allowed you to ask any questions about the procedure and provided you with answers to these questions to the best of their ability. It is important that you read the information contained in this booklet again carefully and completely. Only when you have no questions or concerns do you initial each page, indicating that you have read and fully understood all the items it discusses. When you arrive at the end of the booklet, sign the consent for the procedure as proposed by Dr. Mulholland. If you have any remaining questions about the alternatives, proposed benefits or risks involved in your proposed treatment, do not initial or sign the consents without calling the office at 1-800-561-3376 or (416) 922-2868 and speaking with a SpaMedica® nurse injector or Dr. Mulholland on his pager, (416) 402-7381.

Introduction
A facial injectable is a liquefied substance that is injected under the surface of the skin. The goal of an injectable is to enhance the aesthetic appearance of the patient receiving the treatment. Facial Injectables, may be “fillers”, such as Collagen, Hyaluronic Acid (Hylaform, Restylane or Perlane), and fat all of which fill space under the skin in an attempt to fill up the crevice created by a wrinkle, furrow, scar or depression or augment the size of a facial part such as a lip, eyelid, or cheek.

Collagen is an injectable filler of collagen fibers collected from cows. There are also human versions of collagen, known as Autologen, Dermolagen and injectable fibroblasts called Isologen, none of which are readily available in Canada. Hylaform, Restylane and Perlane are injectable forms of Hyaluronic Acid, a normal constituent of human skin that holds water, providing a plumping effect. Hylaform is harvested from roosters, while Restylane and Perlane are genetically engineered. Both Collagen and Hyaluronic Acids are temporary injectables with clinical effects lasting 6–12 weeks and will require repeat injections to maintain the desired aesthetic influence. Hyaluronic acids have the advantage of being “off the shelf” meaning the reported incidence of allergic reaction is so low, the company does not recommend a skin test. Collagen, on the other hand, has a 3–4% incidence of allergic reaction and will require you to have a pretreatment skin test on two separate occasions that are reported as negative before you may proceed to treatment.
Alternative Treatment

Alternative forms of treatment consist of not electing to undergo facial injectable treatment. Other non-operative treatment options might include chemical or laser peels, facials, Retin-A, or camouflage make-up. Surgical alternatives might include any one or a number of cosmetic surgery procedures, such as implantable products such as gortex (SoftForm) or Alloderm. Each surgical procedure will be associated with its own set of risks and benefits.

Potential Benefits of Facial Injectables

The potential benefits of a facial injectable may include lessening the appearance or depth of a wrinkle, furrow or groove or dampening the activity of a facial muscle, without having to undergo a surgical procedure. The goal is to enhance one’s appearance.

Risks of Facial Injectables

Infection: Any injection, for any reason, carries a small risk of infection. Most infections, should they arise, can be treated with oral antibiotics. Subsequent surgery or drainage may be required.

Bleeding/Bruising: Bleeding can occur as a result of an injectable filler treatment. This may result in bruising or temporary discoloration of the treated area, scabbing, shedding or shallow scarring. To avoid excessive bruising, you must refrain from any Aspirin products for 10 days leading up to your injection.

Herpes Simplex (Cold Sores): If you’ve previously had a facial cold sore (herpes simplex) at the injection site (lips), the injection might provoke an outbreak.

Skin Scarring: In the rare event you have an ulceration, infection or abscess following your injection, a scar may develop. Scars may be large, unattractive and of a different colour than surrounding skin. A subsequent surgical procedure may be required to try to improve the appearance of the scar.

Allergic Reaction: Despite appropriate screening, there is a risk that you may develop an allergic reaction to the injectable or to any local anesthetic (xylocaine) that may be used during the procedure to freeze to area to be injected. The allergic reaction may be minor or more significant and may be life threatening. The use of Collagen requires you undergo skin testing to ensure you do not react.

Abscess: In a small percentage of patients an abscess or small skin boil may develop at the injectable site which might require drainage. An abscess may result in an unfavourable scar.

Temporary Results: The results of your facial injectable may be only temporary and the wrinkle, groove, furrow or overactive muscle may recover or reappear within several weeks or months of your treatment.

Patient Initials __________
Lumpiness: There is a small risk that the injectable may form a palpable or visible lump under the skin. This lump may be aesthetically displeasing and may be temporary or may not go away. Steroid injection or surgical excision may be required to treat this.

Chronic Inflammation/Pain: Very rarely (Collagen 2–3%), your body may react to the injection that causes a red, inflamed lesion (much like a pimple) which takes a long time to resolve, or may never resolve spontaneously. These lesions may also be associated with consistent pain and discomfort. Steroid injection, surgery or other treatments may be required for such reactions following an injectable.

Dissatisfaction With Your Results: You may be disappointed with the cosmetic improvement or longevity achieved with your facial injectable. You may require multiple treatments to achieve the desired result or maintain it.

Immune Reaction: There is a small chance of developing an autoimmune reaction to Bovine (cow) collagen, Hyaluronic Acid or (which has a small amount of collagen carrier in it) which may result in diseases such as Rheumatoid Arthritis, Lupus or Scleroderma.

Asymmetries/Irregularities: The facial injectable may result in visible asymmetries or irregularities in your facial region. More treatments may be required in an attempt to restore balance.

Health Insurance
Most health insurance companies including OHIP, exclude coverage for cosmetic surgical procedures such as injectable substances. Health related complications that may arise from such treatment as usually covered by all insurance plans. Please carefully review your health insurance subscriber-information pamphlet if you have a private insurance carrier.

Additional Surgery Necessary
There are many variable conditions, in addition the risks and potential surgical complications, that may influence the long-term result from your facial injections. Even though risks and complications occur infrequently, the risks cited in this booklet are particularly associated with Facial Injectables. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied as to the results that may be obtained. Infrequently, it is necessary to perform additional surgery to improve your results.
11. I understand that the signature of the witness (if a non-physician) on this document indicates only that the signing of my name has been observed and not that the witness has necessarily provided information regarding the procedure.

12. IT HAS BEEN EXPLAINED TO ME BY MY PHYSICIAN IN A WAY THAT I UNDERSTAND:
   a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
   b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
   c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED
   d. ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1–12). I AM SATISFIED WITH THE EXPLANATION.

__________________________________________
Patient or Person Authorized to Sign for Patient     Please Print Name Here

Date                Witness

Patient Initials __________
FAQs and Answers

Product/Gel-Related Questions

What is the difference between the Q-MED Esthetics products?
The difference between the products is the size of the gel particles (see explanation of tissue tailored concept elsewhere in this file). This can be expressed as the number of gel particles per ml.

<table>
<thead>
<tr>
<th>Product</th>
<th>Gel particles/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESTYLANE® Fine Lines</td>
<td>-200,000</td>
</tr>
<tr>
<td>RESTYLANE®</td>
<td>-100,000</td>
</tr>
<tr>
<td>PERLANE®</td>
<td>-8,000</td>
</tr>
</tbody>
</table>

How are the products produced?
The hyaluronic acid (HA) in NASHA is biosynthetically produced by bacterial fermentation. A specific type of bacteria is used because of its ability to produce a high yield of HA. The HA is extracted and purified. Thereafter it is subjected to a slight chemical modification (stabilization) to increase its longevity in the tissue and to form a gel. The gel is homogenized, filled in syringes and sterilized by moist heat. The syringes are put in blister packs. The blister packs are subsequently put in a carton in which a needle and Instructions for Use are co-packed.

Is there a difference in structure between the products?
All the products are gels. The structure of the gel will be different due to the size of the gel particles.

What is the molecular weight (Daltons) of the Q-MED Esthetics products?
It is not relevant to talk about molecular weight as it cannot be determined for a stabilized gel. The molecular weight of hyaluronic acid in its pure form can be determined. However, hyaluronic acid in its pure form is not stabilized and is therefore not expected to stay in the skin more than a very short period of time.

Has each Q-MED Esthetics product a different molecular weight?
It is not relevant to talk about molecular weight as it cannot be determined for a stabilized gel.

What is the difference between terminally sterilized products and aseptically manufactured products?
There is a 1,000 times higher risk of finding a non-sterile product when using an aseptic manufacturing process.
NASHA is biodegradable. **What is the difference between biodegradation and bioresorption?**
When a material is biodegraded it is decomposed (chemically reduced) into excretable substances by natural biological processes. Bioresorption is the loss of substance through physiological or pathological means. However, in this case some compounds may remain in the organism without being degraded.

**Treatment-Related Questions**

**At what depth in the tissue should the product be injected?**
It is recommended that RESTYLANE Fine Lines be injected into the upper part of dermis.

It is recommended that RESTYLANE be injected into the middle part of dermis.

It is recommended that PERLANE be injected into the deep layer of the dermis and/or the surface layer of the subcutis.

**What happens if the material is not injected into the recommended level of the tissue?**
To ensure satisfactory results it is important that the product is injected at the right level. If the product is injected too deeply, the gel can move in the tissue because the gel particles are too small. If the product is injected too superficially, this might lead to tissue disturbance and/or uneven results because the gel particles are too large in relation to the tissue structure at that level.

**Can the Q-MED Esthetics products be injected using a so-called “sandwich” procedure?**
Yes, e.g. PERLANE can be injected into a deep fold and RESTYLANE and/or RESTYLANE Fine Lines can subsequently be injected at more superficial levels.

**Can Q-MED Esthetics products be combined with other types of implants?**
RESTYLANE Fine Lines, RESTYLANE and PERLANE should not be used together with any other injectable implant. The Q-MED Esthetics products should not be injected into an area where a permanent implant has been placed.

**What needle size should I use?**
A needle is co-packed with each Q-MED Esthetics product, i.e. with RESTYLANE Fine Lines a 31 G needle, with RESTYLANE a 30 G needle and with PERLANE a 27 G needle. Each needle size is matched to facilitate the injection of that specific product. Too small a needle will damage the gel, which might influence the duration of the product in the tissue. Do not, for example, use a 30 G when injecting PERLANE.

**Is there a difference in the force needed to inject RESTYLANE Fine Lines, RESTYLANE or PERLANE?**
No, in practice there is no difference. This is due to the fact that the needle size is matched to facilitate the injection of each product.
How long does the effect of treatment with a Q-MED Esthetics product last?
• Lines, wrinkles and folds:
  In general follow-up treatment is needed after 6–12 months.
• Lips:
  In general follow-up treatment is needed after about 6 months.
But it depends on many factors, such as the structure of the skin, lifestyle, age, the degree of perfection demanded by the patient and the injection technique of the practitioner. Clinical experience indicates that touch-up and follow-up treatment will add to the duration.

Does the material swell after injection?
The composition of the products is set to balance a normal tissue pressure. However, because the tissue pressure is sometimes disturbed to a higher value such as during oedema or to a lower value such as during dehydration, a small but significant change may occur. The patient should be informed about this possibility.

How does the patient notice this change in fluid balance?
Normally, the swelling is noticed if considerable amounts have been injected or when treating the lips. The effect of a decrease in tissue pressure is not so readily visible, as can be seen from the following curve:

This is to say that a relatively large drop in pressure does not give much of a change in volume. On the other hand a relatively small increase in pressure causes a substantially increased volume.

Are there any side-effects or adverse reactions?
Yes, some common injection-related reactions might occur, such as transient erythema, swelling, pain, itching, discoloration or tenderness at the implant site.

Localized reactions thought to be of a hypersensitivity nature have been reported in about one in every 2000 treated patients.

For more information see the Instructions for use enclosed in this file.

Are there more risks associated with PERLANE or RESTYLANE Fine Lines than with RESTYLANE?
No data exist that indicate a difference between RESTYLANE, PERLANE or RESTYLANE Fine Lines from a safety perspective.
Can the products be used for patients during pregnancy or lactation?
Treatment with RESTYLANE Fine Lines, RESTYLANE or PERLANE during pregnancy or lactation has not been tested for.

Are there any known interactions with antibiotics?
Treatment with the products in combination with other drugs and devices has not been tested for. Theoretically there is no basis for an interaction with commonly used antibiotics.

Can patients with different kinds of allergies be more sensitive to the products?
So far we have seen no connection between patients with allergies and patients that report a reaction to RESTYLANE Fine Lines, RESTYLANE or PERLANE.

If a patient has had problems with recurrent facial herpes simplex can treatment with a Q-MED Esthetics product contribute to another herpes simplex eruption?
There is a risk that the injection process itself, i.e. the insertion of a needle into the skin could contribute to another herpes simplex eruption.

Should you give patients suffering from herpes “special” treatment?
The physician should take a decision about the need for prophylactic treatment in consultation with the patient.

Can Q-MED Esthetics products cause hyperpigmentation?
No such problems have been reported.

Can a person suffering from an autoimmune disease be treated with the Q-MED Esthetics products?
Clinical experience of treating patients with an autoimmune disease is very limited, but there is no indication of an increased risk. Theoretically there is no reason to assume that there should be an increased risk in treating these patients with Q-MED Esthetics products. It is at the discretion of the practitioner to decide in each case, taking into account e.g. the specific disease, concomitant medication, etc.

Why do the lips sometimes become very swollen immediately after treatment?
Unfortunately, we do not yet know the cause of this but we have no reason to believe that this is an immunological reaction.

How long does the swelling normally last?
Normally, the swelling is gone within a week after injection into the lips.
What happens if you use laser or chemical peeling on top of an area treated with a Q-MED Esthetics product?
After treatment with a Q-MED Esthetics product you should wait at least 2 weeks before using laser or chemical peeling since an implant always gives a slight, temporary tissue reaction. When using laser or chemical peeling on top of an area that has been treated with a Q-MED Esthetics product it is possible that the heat or induced dermal response has a negative effect on the implant. This has not, however, been scientifically tested.

If a patient has had laser treatment, how long should you wait before treating with a Q-MED Esthetics product?
The Q-MED Esthetics product range is contraindicated for use in connection with all procedures based on active dermal response, which includes laser and chemical peeling procedures. This means that you should wait until the treated area is totally calm and the skin has healed (normally 4–6 weeks).

Which products are recommended for treatment of the lips?
Both RESTYLANE and PERLANE can be used to achieve fuller lips and a pouting look. We recommend that PERLANE be used when sufficient experience with RESTYLANE has been gained. The practitioner should use the product which he/she feels most comfortable with for a specific indication/patient. To enhance the vermilion border RESTYLANE is recommended.

Can PERLANE be used in the glabella area?
Yes, but special attention should be paid to avoid blanching of the skin. See also information in the injection technique part of this file.

Do the products get stiffer, in for example the lips, in cold weather? What happens in the sun?
The patient should not expose the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold for the first few days after the treatment. This is to avoid risk of inflammation since the area has been disturbed. However, once the products are integrated into the body they will adjust to a normal body temperature.

General Questions

What is the CE-number of RESTYLANE Fine Lines, RESTYLANE and PERLANE?
What does it mean?
The CE-number is the same for all Q-MED Esthetics products, CE 0562. This is the number of the notified body. A notified body is an institution which issues the CE-certificate, i.e. gives the CE-mark for products approved for sale within the EU. The CE-mark means that the product fulfils the demands set out in the EU directive.
How is the product tested for registration and quality control purposes?
The raw material in the Q-MED Esthetics products, hyaluronic acid, is produced by bacterial fermentation. This material is purified and depyrogenated in several steps.

The Quality Control analysis performed on the final product consists of a number of different tests:
- identification and concentration of hyaluronic acid
- sterility and endotoxin level
- pH and NaCl content tests for impurities such as heavy metals and solvent residues
- visual inspection

What is the storage time?
At present, the storage time is set at one-and-a-half years after the production date. As our ongoing stability study proceeds, we may get data that support a longer storage time.

How should the products be stored?
The products should be stored at 2–25° C. This means that they can be stored in a refrigerator as well as at normal room temperature. However, if the products are stored in a refrigerator, the gel will become more viscous and thereby very hard to inject.

If the products are stored in a refrigerator, how long before use should they be taken out?
If they have been stored in a refrigerator, the products should be left at room temperature for at least 2 hours before injection.

Will the products be changed in any way when the product is taken in and out of a refrigerator a few times?
No, this will not affect the products.

If the product is just about to expire, will the durability be shorter?
No, the degradation of the products does not start until they are injected.

Restylane Treatment – Patient Questions
This section is also available in pads, which can be given out to interested potential patients.

What is Restylane?
Restylane is a gel that is injected into the skin in order to add volume to the lips and lift up wrinkles or folds.

What is Hyaluronic Acid?
Hyaluronic acid is a natural substance that is found throughout the body. It gives, for example, volume to the skin, lubricates the joints and gives the eye its shape.
How was Restylane developed?
In 1994, after more than 20 years of research, Dr Bengt Ågerup and his company Q-Med in Sweden, managed to develop a way of using a non-animal hyaluronic acid to replace lost skin tissue. Before this, collagen made from cow skin and hyaluronic acid made from rooster combs had been used.

How does Restylane work?
Restylane adds volume to the skin. A physician injects small amounts of Restylane directly into the skin and it lifts up the wrinkle or gives more volume to the lips. Wrinkles can be raised to the level of the surrounding skin and the contours of the lips can be enhanced to the desired level.

What kinds of wrinkles can be treated?
The most common areas are the glabellar lines (between the eyebrows), the nasolabial folds (from the wing of the nose to the angle of the mouth) and the lips, but other sites can also be treated.

What results can be obtained from lip treatment?
The vermilion border can be accentuated and the lips can be given more volume.

What is treatment with Restylane like?
Treatment with Restylane is a very easy and quick process. Since no pre-test is needed, the treatment can be carried out immediately and takes about 30 minutes. The result is instant. Restylane is injected with a very thin needle into the skin.

Can Restylane replace surgical procedures?
No. People with excess facial skin or people who want a major resurfacing of the skin cannot be helped with Restylane. However, Restylane is sometimes used in conjunction with surgery to fill out wrinkles that cannot be removed by surgery.

Do the injections hurt?
This is very individual depending on how sensitive to pain you are. The injections may prick a little but normally no anaesthesia is needed for the treatment of wrinkles and folds. Most people report that the injections are relatively painless. Lip treatment is quite uncomfortable and therefore a nerve block or some similar anaesthetic is normally used.

Can the material be removed?
No, but since Restylane is a natural material it dissolves with time. If you feel insecure about the desired result, it is possible to have the treatment done in steps on different occasions.

Is it safe?
The hyaluronic acid in Restylane is almost identical to that already present in the body and therefore the skin does not react to the material but stays calm and healthy. Also, since the hyaluronic acid in Restylane is not made from animals, there is no risk of transmitting diseases from animals or eliciting allergic reactions to common foodstuffs such as eggs, meat or chicken.
Well over 200,000 treatments have so far been carried out with Restylane and only a very small number of adverse events have been reported (0.05% or 1 out of 2,000 patients). These have mostly been described as mild to moderate swelling, redness and tenderness at the implant site. These symptoms usually subside in 1–2 weeks without any further problems for the patient.

**How will my skin look after the treatment?**
Immediately after the treatment, there may be slight redness, swelling, tenderness and an itching sensation at the treated area. This is a normal result of the injection and the inconvenience is temporary. It generally goes away in a day or two. After lip treatment, the lips may become swollen and look somewhat uneven. This can persist for a couple of days (up to a week). If the inconvenience continues, please contact your physician.

**Is there any other type of reaction that may occur?**
Yes. If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to another cold sore eruption. If you are using aspirin or any similar medication, you should be aware that these may increase the bruising and bleeding at the injection site.

**How long does the effect last?**
Since Restylane is a substance very similar to your own skin, the same ongoing processes (such as ageing) that change the structure of your skin will also alter the implant. Eventually the implant totally disappears from the body. How long the effect of Restylane treatment lasts is very individual. It depends on many factors, such as the structure of the skin, lifestyle and age as well as on the degree of perfection demanded by the individual. Most patients choose to have touch-up treatment done within 6–8 months of the original treatment but for some people the result might last up to one year. For lip augmentation, new treatment is needed after about 4–8 months.

**What will my skin look like without touch-up treatment?**
The correction will gradually disappear until your skin looks just as it did before the treatment. Touch-up injections will help you maintain your correction.
Microfat Grafting, Hyaluronic Acid and Injections

Who is a Candidate?
- If you have indentations in your skin, depressed scars or deep wrinkles.
- If there are grooves, folds or areas of soft tissue depression. This may also include enhancement of your lips.

Intended Results
- Minimize facial and other skin wrinkles and depressions.

Procedure Description
- HYALURONIC ACID: Hylaform and Restylane are forms of hyaluronic acid, a natural component of human skin. These injectable substances hold water, like a sponge, and swell under the wrinkles and folds to smoothen them. Unlike collagen, hyaluronic acid products require no skin testing, as allergic reactions are rare. Results last 6–12 weeks.

- FAT TRANSFER: The patient’s own fat is collected with needles from a distant donor area and reinjected using the microfat techniques to the furrow, hallow or deficient area. The small filaments or toothpicks of fat swell up an area to correct the depression or provide augmentation. Unlike fat grafting techniques in the past, these small filaments are much more likely to pick up a blood supply, avoid resorption or melting away and, as such, provide long-term correction. Microfat is often combined and layered for maximum benefit.

  - All injectables are outpatient procedures.

  - Fat transfer may require sedation plus local anesthesia if larger amounts of fat are to be collected. Small amounts of fat can be collected and transferred under local anesthesia.

Recuperation and Healing
- The treated areas usually look normal within a matter of hours after hylaform injections.

- After Microfat transfer there may be some bruising and swelling for several days, especially in the lips.

Other Options
- Additional procedures that could enhance the result of Hyaluronic Acid Injections or Fat Transfers or other facial cosmetic procedures such as Face Lift, Eyelid Lift, Rhinoplasty, Endoscopic Brow and Lid Lifts, etc.
Insurance Guidelines

• This procedure is considered cosmetic and, therefore, is not covered by insurance. The patient is responsible for payment.

Note:

• The specific risks and the suitability of this procedure for a given individual can be determined only at the time of consultation. All procedures have some degree of risk. Minor complications that do not affect the outcome occur occasionally. Major complications are unusual.

Surgical Fee Range:

• Hyaluronic Acid ranges from $300.00 to $1,000.00.

• Microfat ranges from $3,000.00 to $6,000.00.
Facial Injectables

<table>
<thead>
<tr>
<th>Date</th>
<th>Area Injected</th>
<th>Product</th>
<th>Amount</th>
<th>Lot#</th>
<th>?? Pt. Pregnant</th>
<th>ASA Products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes:

____________________________

Client name: ____________________________

INITIALS

SpaMedica® Franchisee Clinical Training Manual

IX - 8.1
The Skin – A Quick Review

The Skin

- The skin can be divided into two main layers, epidermis and dermis.
- The dermis contains hyaluronic acid (interstitial substance), collagen and elastic fibers.
- Subcutis is not a part of the skin, but closely related to it.
- Old skin contains less HA, which is one of the reasons for the creation of wrinkles.

Epidermis and Dermis

The skin, although not often viewed as an organ, is in fact one of the larger organs of the human body in terms of surface, area and weight.

The skin can be divided into two main layers:
1. epidermis
2. dermis

The outermost layer of the skin, the epidermis, is comprised of closely packed epithelial cells. The epidermis is usually quite thin, not exceeding 0.12 mm over most of the body.

Beneath the epidermis lies the dermis. The main function of the dermis is to provide a tough matrix to support many structures embedded in it, i.e. vessels, nerves, and various appendages. The dermis is thicker than the epidermis, ranging from 0.6 mm on the eyelids to as much as 3 mm on the soles and palms. The dermis contains interstitial substance (hyaluronic acid) as well as elastic and collagen fibers. Hyaluronic acid in the interstitial substance has a very important function in that it binds water and thereby creates the volume of the skin. With age, the skin loses its ability to produce hyaluronic acid and it does not hold water as well as before. This is one of the reasons why wrinkles are created.

Subcutis

The subcutaneous tissue, while not a part of the skin, is very closely related to it. Subcutaneous fat occurs almost universally over the body surface but it is absent from the eyelids and the male genitalia. It acts as an insulating layer and as a protective cushion, and it also has an important role in thermogenesis, and as a store of readily available energy. In a normal person, fat constitutes about 10% of the body weight. Fat also provides support and has a cosmetic function, e.g. in the contours of the face.

Muscles are present in the subcutaneous tissue, blood vessels and lymphatics travel through it in going to and from the skin and many sweat glands and hair follicles extend down onto it.
Wrinkles and Folds
Facial wrinkles are produced by repeated and habitual contraction of the underlying muscles of facial expression. When the facial muscles contract, the muscles shorten without a corresponding shortening of the overlying skin, thereby producing a wrinkle. Other factors that cause aging of the skin are the thickness of the skin and amount of underlying fat, the water content of the skin, the distribution and ratio of collagen and elastic fibers and the biochemical changes in the connective tissue interstitial substance. Various changes occur with aging which create wrinkles. Of these changes, the alterations in interstitial substance are one of the most important. The interstitial substance becomes less clear and old skin contains less hyaluronic acid.
Pain Management

For Injectable Fillers

1. SpaMedica® has a variety of anaesthetics to assist the client with management of pain.

2. Num-it™ cream, a topical anaesthetic, contains Benzocaine, Lidocaine, and Tetracaine. There is also Benzocaine-free Num-it™. The cream is applied to the treatment area thick enough that you cannot see the skin below. This product will begin to numb in about 15–20 minutes. For optimal numbness of areas clients can purchase this product for $29.95 and apply up to an hour prior to treatment.

3. Our cryo cooler can be used in conjunction with Num-it™ or on its own. The cryo cooler blows cold air from a hose which is directed by either client or nurse. This will drop the temperature of the skin so the injection can be virtually painless.

4. Local anaesthetic can also be used to anaesthetize the upper and lower lips to permit painless injection for lip augmentation. Please see following pages for specific technique.

5. Be sure client is comfortable and pain-free at all times. This may mean treatment must be stopped to deliver more anaesthetic to the treatment area.

6. Be aware of client’s conscious state; some clients can become lightheaded quite easily and must be placed in a supine position until this passes. K-basins, BP cuffs, and washcloths are located in the recovery room. Cold juice is available if needed.
Pain Management

Some kind of anaesthesia is generally necessary in connection with lip augmentation. This is achieved most effectively by a nerve block or by local anaesthesia.

Technique for nerve block (infra-orbital and/or mental nerves)

To anaesthetize the upper lip: feel the gingiva of the upper teeth to locate the canine eminence (corresponding to the socket of the canine tooth). Just lateral to it or between the 3rd and 4th tooth at the mucosal fold you inject 0.5–1 ml of lidocaine 10–20 mg/ml.

For the lower lip: locate the mucosal fold between the premolars (4th and 5th tooth) and inject as above.

Local Anaesthesia

The application of a local anaesthetic cream, such as EMLA (available from Astra Pharmaceuticals), to the area to be treated can be effective. It is usually not sufficient to use EMLA when giving full lip treatment, but it can be used when treating only the lip line. EMLA cream needs to be thickly applied and covered by an occlusive dressing for at least 45 minutes (20 minutes for the lip line) prior to the treatment. It is best to remove the dressing and any excessive EMLA cream a few minutes prior to injection. In some instances it has been reported that the cream hydrates the skin, thereby partially obscuring fine lines and making full and accurate correction difficult. Plastic cling film has been used successfully as an occlusive dressing to cover the EMLA cream. Some patients find the whole exercise messy and time-consuming but in committed patients it can be an effective pain management technique.
To achieve pouting of the lip by injecting superficially under the mucosa or before administering a nerve block, you can use lidocaine spray (10 mg/dose), 1–5 doses on the injection site.

**Objective**
Local anaesthesia technique to anaesthetize upper and lower lips to permit painless injection of Restylane/Perlane in lips only.

**Supplies:**
- topical anaesthetic
- 6 inch cotton tip applicators
- cotton rolls or 2 x 2 gauze
- non epinephrine/adrenaline local anaesthetic (disposable carpules preferred)
- disposable syringe (aspirating preferred)
- disposable 30 gauge short needles
- latex gloves

**Medical History**
Check to make sure that patient has no allergies to latex, topical anaesthetics, local anaesthetics

**Technique**
Goal is to give pain-free injection. Warm up anaesthetic (run syringe under warm water), don’t need to put needle in too deep, inject very slowly, about 1.0 ml in each injection site.

Before injecting anaesthetic it is important to evaluate area that you will be treating. The anaesthetic may distort the lips making them look swollen.

Before applying topical anaesthetic dry area with gauze or cotton rolls.
Apply small amount of topical to the area that you will be injecting into.
Wait 2–3 minutes before injecting.

**Upper Lip**
Inject 1.0 ml local anaesthetic. Lift the upper lip and infiltrate into soft tissue above eye teeth (cuspids) on either side.
This should be enough to make lip numb from one corner of upper lip to the other corner.

**Lower Lip**
Inject 1.0 ml local anaesthetic. Pull back lower lip and infiltrate into soft tissue below and between 1st and 2nd premolars (bicuspids) on either side.
This should be enough to numb lower lip from one corner of lower lip to the other corner.
Wait about 5 minutes before starting to inject Restylane. Patient should be able to tell you if he/she is still feeling pain while injecting Restylane. If necessary you can put in more anaesthetic in similar areas or move over more to the front teeth on top and bottom.
**Trigeminal Nerve**

The Trigeminal Nerve (CN V) is the fifth Cranial Nerve and divides into three branches.

i) Ophthalmic Nerve (V-1)

ii) Maxillary Nerve (V-2)

iii) Mandibular Nerve (V-3)

For our purpose the Maxillary and Mandibular Nerves are the branches of interest.

**Maxillary Nerve (V-2)**

This is a sensory nerve that breaks up into six branches

1) Meningeal branches

2) Ganglionic branches

3) *Posterior superior alveolar nerves* – supply the maxillary sinus and the roots of the maxillary molar teeth (except the mesiobuccal root of the first molar)

4) *Middle superior alveolar nerve* – supply the sinus mucosa, the roots of the maxillary premolars and the mesiobuccal root of the first molar

5) *Anterior superior alveolar nerve* – leaves the infraorbital portion of the maxillary nerve just before the infraorbital nerve issues onto the face. The alveolar branch descends through its own canal in the anterior wall of the maxillary sinus and sends branches to the sinus, a portion of the nasal septum and the roots of the maxillary central, lateral and canine teeth.

6) *Facial branches* – radiate from the infraorbital foramen and supply the lower eyelid, nose, and upper lip.

In dentistry when working on multiple anterior teeth it is feasible to perform an infraorbital nerve block. This would provide analgesia to the anterior superior alveolar and the facial branches of the Maxillary Nerve. Ultimately, bilateral infraorbital nerve blocks would provide anesthesia to the upper lip. This, however, could also be achieved by local infiltration apical to the root tips of the six anterior teeth.
Mandibular Nerve (V-3)

This is both a sensory and motor nerve that divides into seven branches

1) Nervous spinosus (sensory)
2) Nerve to the medial ptergoid (motor)
3) Motor branches – supply muscles of mastication (temporalis, masseter, and lateral ptergoid muscles.
4) Long buccal nerve (sensory) – supplies the cheek and Mandibular buccal gingiva.
5) Auriculotemporal nerve (sensory) – sends sensory branches to the jaw joint, auricle, external auditory meatus, and skin of the temple and lateral scalp.
6) Lingual nerve (sensory) – supplies sensory fibers to the mucous membrane of the floor of the mouth, Mandibular lingual gingiva, and mucous membrane of the anterior two-thirds of the tongue. It also carries hitchhiking fibers of the chorda tympani, which supply special sensory taste.
7) Inferior alveolar nerve (sensory and motor) – travels inferiorly deep to the lateral ptergoid muscle and on reaching the inferior border of the muscle, turns laterally to enter the mandibular foramen located on the medial surface of the ramus of the mandible. Prior to entering the foramen, a slender motor branch is given off, that passes downward and anteriorly to the submandibular region to supply the mylohyoid and the anterior bellies of the digastric muscle. The inferior alveolar nerve passes through the mandibular canal and as it passes below the roots of the mandibular teeth, it sends sensory twigs to the apical foramina. In the region of the premolar, a mental branch is given off that turns laterally to emerge through the mental foramen onto the face. Here it divides to supply sensory branches to the skin of the chin, the mucous membrane and skin of the lower lip, and labia mandibular gingiva.

If one were attempting to provide analgesia to the lower lip, bilateral mental branch nerve blocks would be very effective.
The Treatment Session

Initial Consultation

- Inform the patient about the procedure and the possible outcome as well as of the possibility of side-effects. Answer any questions or address any concerns they may have. A brief medical history should be taken with special reference to any bleeding disorders or previous skin therapies, e.g. tissue augmenting or laser and peeling procedures.

- Management of the patient’s expectations. It is recommended that the reason for the patient seeking treatment and the suitability of the treatment modality for the site and indication be discussed. Remember that the patient cannot have treatment with Q-MED Esthetics products concurrent with treatment by laser or chemical peeling. Pre-treatment photos are recommended.

- It is necessary to counsel the patient and discuss the appropriate indication, risks, benefits and expected responses to the Q-MED Esthetics treatment. The practitioner needs to stress that Q-MED Esthetics Products consist of NASHA (Non-Animal Stabilized Hyaluronic Acid) which is a gel almost identical to the body’s own hyaluronic acid. Treatment with Q-MED Esthetics restores the contours of the skin and diminishes lines, wrinkles and folds by adding volume to the tissue.

- The patient needs to know that touch-up treatment might be necessary to achieve full correction, and that if the defect cannot be removed by manual tension then the treatment may not be totally successful. The patient should be given a Q-MED Esthetics patient brochure to read.

- How long the effect of Q-MED Esthetics treatment lasts is very individual. It depends on many factors, such as the structure of the skin, lifestyle and age as well as on the degree of perfection demanded by the individual and the injection technique of the practitioner. In general, follow-up treatment is needed after 6–12 months for the treatment of lines, wrinkles and folds and facial contouring. For lips, follow-up treatment is normally needed after about 6 months. Clinical experience indicates that touch-up treatments will add to the duration of the treatment effect.

- Some areas of the face are used almost continuously (e.g. the mouth) or the skin may lie over very strong muscles (e.g. the glabella area). This may affect the longevity of the product.
• Advise the patient that the treatment will take approximately 30 minutes. The patient needs to be informed that the result directly after the treatment may not be the final result, depending on the extent of injection-related localized swelling (N.B. this is especially important after lip treatment).

• Advise the patient of the necessary precautions before commencing the procedure.

• It is recommended that informed consent is obtained from the patient by using the Q-MED Esthetics Consent Form (see sample included in this file).

_Treatment with Q-MED Esthetics_

• Remove any make-up and clean the treatment site with alcohol or another suitable antiseptic solution. Pain management needs to be considered.

• Q-MED Esthetics products should be administered using the needle that is co-packed with each product. The injection technique with regard to the depth of the injection and the quantity administered may vary. For a detailed description of the injection technique.

• Attach the patient record label (part of the syringe label that can be removed by pulling the flap marked with the 3 arrows) on the Patient Record Form. This is very important since it ensures traceability of the product.

_Post-treatment_

• Give the Q-MED Esthetics Post-Treatment Checklist to the patient.

• Call the patient at the end of the day, or the following day, to make sure that he/she is satisfied.

• It is recommended that touch-up treatment be considered for the patient after 2–4 weeks to achieve optimal results.

_Pouting and fullness_

To achieve pouting and/or fullness both RESTYLANE and PERLANE can be used. If you do not have previous experience of using a Q-MED Esthetics product for lip augmentation we recommend that you start with RESTYLANE. Whether RESTYLANE or PERLANE should be used is otherwise at the discretion of the practitioner, taking into account the patient’s wishes and other prerequisites for the treatment.

_Pouting of the lip_ can be achieved by injecting the product 2 mm above (oral to) the mucocutaneous (wet-dry) border which can be seen as a whitish streak along the inside of the lip. Normally the middle part (⅓–⅔) of the upper and/or lower lip is treated in this way, but this must of course be adapted to suit the patient in question.
Fullness of the red part of the upper lip is obtained by inserting the needle 4–5 mm from the lateral part of the middle section of the lip. The product is injected while pulling the needle backwards. The injection should stop 4–5 mm on the contralateral side of the middle section of the lip. The eye of the needle should face the interior of the lip.

When using this technique it is very important to inject 2 mm under the skin (in the dermis) all the time. Injection into the deeper muscular part of the lip should be avoided because of the risk of creating a hematoma and also because of the quicker resorption of the implant.

Normally, the lower lip has more volume than the upper lip. Therefore, in most cases it is not necessary to treat the red part of the lower lip. In case this should be needed or asked for, the same technique as for the upper lip should be used and then it is usually only necessary to treat the middle part (about ⅓ of the lower lip).

N.B. The procedure can easily cause swelling in the lips. It is therefore very important to inform the patient that the result directly after the treatment is not the final result. The swelling normally lasts for 3 days and the lips can look asymmetrical during this period because of the oedema from the anaesthesia and the injections. If the asymmetry is still present after 10 days it should be corrected. Be sure that you inject the same amount of gel in the right half as in the left half of the lip. The lips are a highly sensitive part of the body and therefore anaesthesia is usually required before treatment (see the Pain Management section in this file).
Overview of Indications

- Worry Lines
  - RESTYLANE Fine Lines

- Nasolabial folds
  - RESTYLANE, PERLANE

- Vermilion border
  - RESTYLANE

- Glabellar lines
  - RESTYLANE

- Periorbital lines
  - RESTYLANE Fine Lines

- Cheek augmentation
  - PERLANE

- Perioral lines
  - RESTYLANE Fine Lines

- Smile lines
  - RESTYLANE, RESTYLANE Fine Lines

- Lip augmentation
  - RESTYLANE, PERLANE

- Chin augmentation
  - PERLANE

- Oral commissures
  - RESTYLANE, PERLANE
### Summary per Product

<table>
<thead>
<tr>
<th></th>
<th>RESTYLANE Fine Lines</th>
<th>RESTYLANE</th>
<th>PERLANE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composition</td>
<td>20 mg/ml stabilized hyaluronic acid</td>
<td>20 mg/ml stabilized hyaluronic acid</td>
<td>20 mg/ml stabilized hyaluronic acid</td>
</tr>
<tr>
<td>Approximate number of gel particles per ml</td>
<td>200,000</td>
<td>100,000</td>
<td>8,000</td>
</tr>
<tr>
<td>Recommended indications</td>
<td>Thin superficial lines, such as worry lines, periorbital lines, perioral lines</td>
<td>Wrinkles, such as glabellar, oral commissures&lt;br&gt;Lips: Fullness, pouting and vermilion border</td>
<td>Folds, such as nasolabial folds&lt;br&gt;Shaping facial contours: e.g. cheeks and chin&lt;br&gt;Lips: Fullness and pouting</td>
</tr>
<tr>
<td>Where to inject</td>
<td>Uppert part of dermis</td>
<td>Middle part of dermis</td>
<td>Deep layer of dermis and/or surface layer of subcutis</td>
</tr>
<tr>
<td>Recommended degree of correction</td>
<td>100% No overcorrection</td>
<td>100% No overcorrection</td>
<td>100% No overcorrection</td>
</tr>
<tr>
<td>Volume of syringe</td>
<td>0.4 ml</td>
<td>0.7 ml and 0.4 ml</td>
<td>0.7 ml</td>
</tr>
<tr>
<td>Needle size</td>
<td>31 G</td>
<td>30 G</td>
<td>Up to 27 G</td>
</tr>
</tbody>
</table>
**Recommended Injection Techniques**

A. Smoothing Lines, Wrinkles and Folds

*Wrinkles: RESTYLANE*

RESTYLANE is to be implanted through a 30 gauge needle in the middle part of the dermis layer of the skin. The linear threading technique, the serial puncture technique, or a combination of the two can be used depending on preference and treatment area.

**Linear threading technique**

![Linear threading technique](image)

The full length of the needle is inserted in the middle of the wrinkle. RESTYLANE is injected while pulling the needle slowly backwards. The “threads”, each approximately 10 mm long, are injected lengthwise in the wrinkle. Together the threads will form one single string, lifting the wrinkle to the desired level of correction.

**Serial puncture technique**

![Serial puncture technique](image)

Multiple injections are placed serially along the length of the treated wrinkle/fold. The serial placements of the product within the skin should join together into a smooth continuous line. There should be no spaces between the injected material.

**Volume augmentation**

![Volume augmentation](image)

RESTYLANE works by volume augmentation. Small amounts of the product are injected directly into the dermis. The effect of the treatment is not dependent on active tissue reaction.
Step-by-step

1. Assess the patient’s need for pain relief. Normally, no pain relief is necessary when injecting into the skin for the correction of wrinkles. If the patient needs pain relief, EMLA cream (Astra Pharmaceuticals) can be thickly applied to the area under an occlusive dressing at least one hour prior to the treatment (see the Pain Management section in this file).

2. Clean the area to be treated with alcohol or another suitable antiseptic solution.

3. The needle (30 G x ¼") is inserted at an approximate angle of 30° parallel to the length of the wrinkle or fold. The bevel of the needle should face upwards and the substance should be injected into the middle of the dermis. Tip: for mid-dermis placement the contour of the needle should be visible but not the colour of it.

4. Inject RESTYLANE applying even pressure on the plunger rod while slowly pulling the needle backwards. The wrinkle should be lifted and eliminated by the end of the injection. It is important that the injection is stopped just before the needle is pulled out of the skin to prevent material from leaking out or ending up too superficially in the skin. Only correct to 100%. Do not overcorrect.

5. When the injection is completed the treated site should be massaged so that it conforms to the contour of the surrounding tissues. If you have an overcorrection, massage it firmly between your fingers or against an underlying superficial bone to obtain optimal results.

If so called “blanching” is observed, i.e. the overlying skin turns a whitish colour, the injection should be stopped at once and the area massaged until it returns to a normal colour.

6. If the wrinkle needs further treatment, the same procedure is repeated with several punctures of the skin until a satisfactory result is obtained. Additional treatment with RESTYLANCE may be necessary to achieve the desired correction. With patients who have localized swelling the degree of correction is sometimes difficult to judge at the time of treatment. In these cases, it is better to invite the patient to a touch-up session after 1–2 weeks. Periodic follow-up injections may be required to sustain the desired degree of correction.
7. In some cases, a second layer of RESTYLANE or RESTYLANE Fine Lines can be injected into residual/overlying superficial lines to achieve an optimal effect.

Lines: RESTYLANE Fine Lines

1. RESTYLANE Fine Lines should be injected through a 31 gauge needle into the upper part of the dermis. Anaesthesia is normally not necessary when injecting RESTYLANE Fine Lines.

2. For RESTYLANE Fine Lines the same general injection technique as for RESTYLANE can be applied, i.e. either the serial puncture or the linear threading technique. Since RESTYLANE Fine Lines should be placed more superficially than RESTYLANE it is usually an advantage to have the bevel of the needle facing downwards, especially when using the serial puncture technique.

3. A common indication for RESTYLANE Fine Lines is the periorbital lines (or crow’s feet). There are some very superficial veins in this area and to avoid hematomas it is not recommended that lines which lie within the orbital rim (the bony edge surrounding the eye) be treated.

Folds: PERLANE

Assess the patient’s need for pain relief (see Pain Management). The treatment with PERLANE may be perceived as more painful than with RESTYLANE because of the slightly larger needle and the more viscous nature of PERLANE.

PERLANE should be injected through a 27 gauge needle into the deep dermis and/or the surface layer of the subcutis.

For the correction of folds it is recommended that the linear threading technique be used (see the injection technique for RESTYLANE) and inject at the level of the deep dermis.
B. Shaping Facial Contours: PERLANE

To shape the facial contours with PERLANE two different techniques have been successfully employed.

1. The “fan” technique: insert the needle at the periphery of the area intended to be augmented as when using the linear threading technique. After injecting one line do not withdraw (exit) the needle from the skin. Instead, change the direction of the needle and inject as before along a new line (see figure) and repeat this in a “fan” shaped fashion. In this way a relatively large area can be covered while minimizing the number of puncture sites in the skin.

2. The “cross-hatching” technique: insert the needle at the periphery of the area intended to be augmented and inject as when using the linear threading technique. Withdraw the needle from the skin and insert it 5–10 mm adjacent to the first puncture site and inject in the same way. This procedure can then be repeated from different sites around the area to be treated and at slightly different levels (see figure).

If there is any visible unevenness the treated area can be gently massaged.
C. Lip Sculpting

Lip augmentation with Q-MED Esthetics can be divided into the following steps:

1. Contouring
2. Pouting and fullness

First of all it is important to have a good knowledge of the anatomy of the lip to achieve the best results for every patient.

1. Contouring:

The first time you perform lip augmentation it is recommended that you start by using RESTYLANE to augment the lip line (vermilion border), i.e. where the lip turns from red to white. The needle should be inserted along the length of the lip line from the philtrum ridge to the corner of the mouth. The injection should start from the middle of the lip (the philtrum) and stop at the corner of the mouth. To make the lip line more visible while injecting it is helpful to squeeze the lip between the thumb and the index finger. The gel is injected while pulling the needle slowly backwards. The procedure is repeated until the full length of the vermilion border has been treated. The area can be gently massaged if there are signs of unevenness.

The philtrum ridges can be defined by using RESTYLANE. Start by inserting the needle at the vermilion border upwards towards the nose and inject with the linear threading technique along the ridges.
The Q-Med Esthetics Product Range

Nasolabial and Oral Commissures before

Nasolabial and Oral Commissures after

Glabellar before

Glabellar after

Glabellar before

Glabellar after

Periorbital before

Periorbital after

BASED ON NASHA

NON-ANIMAL STABILIZED HYALURONIC ACID
**Benefits**

- Non-animal
- No skin test needed
- Biodegradable
- Long-lasting
Treatment of Acne Scars

Technique Guide
The following illustrations demonstrate the recommended treatment for acne scars.

Before we begin...
- Review with the patient the indication to be treated.
- Cleanse the treatment area.
- Be sure the patient is sitting in an upright position.

1) Evaluate all scars from frontal, profile, and side view. Decide which scars will respond by performing the stretch test. You may want to identify treatable scars with a marking pen.

2) Beginning in the center of the scar, inject product into the reticular dermis at a 45° angle to the skin’s surface. A delayed, but transient blanch will appear that will cover the circumference of the scar.

3) Massage treated area after each injection.
4) A series of injections may be needed to achieve full correction. Continue injecting the portion of the scar still indented, followed by massage.

5) Full correction.

Things to remember:

• A stretch test may be performed (by pulling the skin taut) on each scar to assess optimal treatment capability. If the scar is eliminated when the skin is pulled taut, full correction may be achieved.

• Ice pick acne scars are not candidates.
Treatment of Nasolabial Lines

Technique Guide
The following illustrations demonstrate the recommended treatment technique for nasolabial lines or furrows.

Before we begin...
- Review with the patient the indication to be treated.
- Cleanse the treatment area.
- Be sure the patient is sitting in an upright position.

1) Before treatment.

2) Inject product into the reticular dermis at a 45° angle to the skin’s surface. A slightly delayed blanch will be observed with proper placement. Using a serial puncture technique, begin injecting at the lower end of the furrow.

3) Massage the area promptly using a double-sided massage. Continue to massage each area after every 2–5 injections.
4) Continue with the same technique on the other side.

5) Full correction.

**Layering Technique:**

Often the nasolabial lines or furrows are best treated with a layering technique using a combination of Perlane and Restylane injected in the papillary dermis at a 10° angle as a second layer to fill in residual lines and provide a softening effect. When placed properly, an immediate blanch and wheal will be observed, indicating correct placement in the superficial layer.
4) Continue with the same technique on the other side.

5) Full correction.

**Layering Technique:**

Often the nasolabial lines or furrows are best treated with a layering technique using a combination of Perlane and Restylane injected in the papillary dermis at a 10° angle as a second layer to fill in residual lines and provide a softening effect. When placed properly, an immediate blanch and wheal will be observed, indicating correct placement in the superficial layer.
Treatment of Oral Commisures

Technique Guide
The following illustrations demonstrate the recommended treatment technique for oral commissures, using an injection patch resembling a “triangle”.

Before we begin...

• Review with the patient the indication to be treated.
• Cleanse the treatment area.
• Be sure the patient is sitting in an upright position.

1) Before treatment.

2) The triangle technique is made up of three injection paths that resemble a triangle (as shown above).

3) Injection A: Beginning at the distal end of the commissure, inject toward the corner of the mouth at a 45° angle to the skin’s surface using a serial puncture technique. A slightly delayed blanch will be observed with proper placement.
4) *Injection B*: To form the second side of the triangle, begin at the distal end of the commissure and inject at approximately a 30° lateral angle to injection A. Inject toward the lower lip using a serial puncture technique.

5) *Injection C*: To complete the triangle, begin injecting into the vermilion border of the lower lip at a 10° angle to the skin’s surface using a linear threading technique. Massage by pinching the treated area to form a ridge or defined border.

6) Full correction.

*Note*: In some cases of deep oral commissures, the triangle method may leave a small indentation in the center of the triangle. If this should happen, inject into the center of the triangle at a 45° angle to the skin’s surface, using a serial puncture method. One to three injections is typical.

*Things to remember:*

- Massage each treated area after every 2–5 injections.
Treatment of the Vermilion Border

Technique Guide
The following illustrations demonstrate the recommended treatment for the vermilion border.

Before we begin...
- Review with the patient the indication to be treated.
- Cleanse the treatment area.
- Be sure the patient is sitting in an upright position.

1) Before treatment.

2) Grasp the vermilion border between your fingers. Place the needle between your fingers and thread it into the vermilion border at a 10º angle to the skin’s surface.

3) Ideally material should track along the vermilion border renewing its definition. You should feel the material tracking between your fingers. Use a double-sided massage to mold the border.
4) Inject product superior to the vermilion border below the philtrum. Approach the area with the syringe parallel to the angle formed by the upper lip.

5) Complete the treatment by injecting product along the vermilion border beneath the lower lip. Inject as shown above. To mold the border, pinch between fingers and roll down.

6) If desired, a slightly downturned corner of the mouth may be uplifted. Begin by injecting product directly into the vermilion border towards the eye. Inject as shown above, allowing the material to track upward to the most lateral aspect of the upper lip. Massage the treated area after each injection.

7) Full correction.

Things to remember:

• Pinching the vermilion border keeps product at the border and is less painful for the patient.
Treatment of Glabellar Lines

Technique Guide
The following illustrations demonstrate the recommended treatment for glabellar lines.

Before we begin...
- Review with the patient the indication to be treated.
- Cleanse the treatment area.
- Position the patient in such a way as to achieve optimal control and view of the area to be treated. You may consider positioning the patient in a reclined or semi-reclined position when treating the glabellar region.

1) Before treatment.

2) Inject directly into the line at a 10–15° angle to the skin’s surface. Inject using a serial puncture technique parallel or perpendicular to the line. An immediate blanch and wheal should be observed with proper placement.

3) A slight massage may be desired to check for any gaps or inconsistencies.
4) Continue with the same technique on the other side.

5) Full correction.
Restylane/Perlane Post Treatment Instructions

1. Immediately after the treatment, there may be slight redness, swelling, tenderness, bruising and an itching sensation in the treated area. This is a normal result of the injection. The inconvenience is temporary and generally disappears within a few days. If the inconvenience continues, or if other reactions occur, please contact the clinic.

2. The initial swelling after lip treatment may last longer. Some patients experience swelling for about a week and the lips can look somewhat uneven during that time. This means that the result directly after the treatment should not be seen as the final result. You should massage the injected areas as instructed in order to smooth and soften any lumpy areas. Cool compresses for 48 hours may help to reduce swelling. Bruising in all treated areas may last up to a week.

3. The treated areas may be washed with soap and water. If required, light makeup may be applied with clean fingers following treatment.

4. Until the initial swelling and redness have resolved, do not expose the treated area to intense heat (e.g. solarium and sunbathing).

5. If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to another eruption of cold sores.

6. If you are using aspirin or any similar medication, be aware that these may increase the bruising and bleeding at the injection site.

7. Most patients find that since Restylane and Perlane gradually dissolve, treatments need to be repeated approximately 2–3 times per year. If you are interested in more long-term options, please contact the clinic.

8. If you have any questions or concerns, please contact SpaMedica® at (416) 922-3743 or after business hours, you can call Dr. Mulholland’s pager: (416) 402-7381.
The First Clinical Study Using a New Biodegradable Implant for the Treatment of Lips, Wrinkles, and Folds

Michael Olenius, M.D.
Kirurg-Centrum, Stockholm, Sweden

Abstract. A new tissue augmentation product, made from hyaluronic acid, was clinically evaluated at three clinics in accordance with the new directive, EN 540, for medical implants. One hundred patients were fully assessed following treatments in 285 locations. The treatment was completed when the skin was levelled following one to two injections. At 6 months follow-up of all patients and at 12 months follow-up of a randomized group of the patients all showed that close to 60% of the effect was still there. No serious or permanent adverse events were noted.

Key words: Hyaluronic acid—Hyaluronan—Implant—Wrinkle—Bioimplant

The aging skin is a challenge to the aesthetic therapist. Following treatment with ointments, more profound wrinkles and folds need more effective correction through tissue augmentation. One such product has been used for more than a decade. It is based on bovine collagen and has been found to be sensitizing, short-lasting, and, in recent years, also a potential source for the transmittal of certain viral diseases.

To date, a wide variety of other materials have been used for repairing depressed contour deformities, e.g., teflon, silicone, gold, collagen, and most recently, cross-linked hyal, a rooster comb derivative of hyaluronic acid [1,2,4,5,7,8,13]. The commercial preparations of these materials have not appeared to have all the properties of an optimal substance, such as pronounced tissue augmentation, transparency, nontoxicity, a long-lasting effect, and biodegradability. Thus, a safe and long-lasting, yet degradable, implant is in great demand for use in the growing practice of tissue augmentation of the aging skin. Hyaluronic acid is a natural polymer with extraordinarily good biological compatibility. It is a constituent of all connective tissues in humans and most other vertebrae (1). However, the preparations available at present have proved to have some significant shortcomings. Most importantly, hyaluronic acid extracted from rooster combs has proved to be potentially sensitizing to some individuals if it is not highly purified [10,11]. Secondary, nonmodified preparations do not last for more than 2 days in the intradermal space in rabbits [9].

In contrast, stabilized hyaluronic acid is designed to elicit isovolemic degradation for at least a year (Restylane from Q-Med AB). The source of the raw material is nonanimal cells and it is therefore not associated with the safety drawbacks of rooster comb hyaluronic acid. The stabilized formulation is designed to give a long duration, while remaining biocompatible and injectable. Trials in several animal species indicate that a stabilized form of hyaluronic acid does not elicit humoral or cell-mediated immune reactions, and that it is noninflammatory, nontoxic, and not recognized as a foreign body in the tissue [3].

Objective

The primary objective of the study was to investigate the safety and efficacy of stabilized hyaluronic acid when injected intradermally to correct wrinkles and folds in the face. The secondary objective was to investigate device performance after implantation.
to the actual injection of the bulking agent were seen in about 8% of the sites and dissolved within the first week following the treatment (Table 3).

A few events were noted to occur during the follow-up, but were not associated with the device. These are listed in Table 4. No adverse events were found to be related to the actual implant.

Finally, a few events were noted that seemed to be associated with the technique used when injecting the device (Table 5). It is quite easy to obtain too superficial an implantation of the device with concomitant optical phenomena or to inject the material unevenly. It is also worth noting that a material that exhibits a long residence time in the skin is likewise a source of entrapment of mainly hemoglobin emanating from the small bleedings often found during the injections. This will show up as darker spots.

Discussion

Materials used for the purpose of implantation in the dermal area of the skin have differed over the years. Due to the living nature of the skin, permanent implants have been shown to be less desirous. Corrections are some-

---

Table 1. Physicians’ evaluations of area feeling, texture and color. (The figures denote the number of sites, expressed as a percentage)

<table>
<thead>
<tr>
<th>Area feels</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>looser</td>
<td>same</td>
<td>somewhat firmer</td>
<td>much firmer</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>91</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>57</td>
<td>41</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>42</td>
<td>51</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>86</td>
<td>14</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>87</td>
<td>10</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Week 26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>93</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Week 52</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>97</td>
<td>*</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Week 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>99</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>98</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>96</td>
<td>0</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Week 52</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* = The scale at week 0 was 2-graded: "The same" or "Different."

---

Table 2. Patients’ evaluations of area feeling, texture and color. The figures denote the number of sites, expressed as a percentage.

<table>
<thead>
<tr>
<th>Area feels</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>looser</td>
<td>same</td>
<td>somewhat firmer</td>
<td>much firmer</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>93</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>55</td>
<td>44</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>41</td>
<td>52</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>71</td>
<td>28</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>83</td>
<td>16</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Week 26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>90</td>
<td>5</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 52</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>97</td>
<td>2</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Week 0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>94</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>96</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>97</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>97</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Week 26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Week 52</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* = The scale at week 0 was 2-graded: "The same" or "Different."
avoiding any form of impurity that may stem from animals, as with hyaluronic acid from chickens.

The method of stabilizing hyaluronic acid in this case results in a very small modification of the natural hyaluronic acid molecule in the range of a mere 0.5%–1%. The long residence time is obtained through the formation of intermolecular bonds. This leads to an indefinitely large network that is only physically broken down to 100-μm fragments to allow the hyaluronic acid to be injected. The net result of this is a material that is essentially similar to and as well tolerated by cells and tissues as its unmodified native origin, but with a residence time that is at least 100 times as long.

Conclusion

Stabilized hyaluronic acid fulfilled the expectations of giving a safe and efficient tissue augmentation.

References

3. Company Reports Q-Med Sweden, Seminariegatan 21, 752 28 Uppsala, Sweden
Acknowledgment of Complete Comprehension

I __________________________, franchise trainee, on this date of ______________ have carefully read and have a thorough understanding of every page of this chapter. I have initialed each page that signifies I have no further questions whatsoever regarding the information in this chapter, and that all my questions have been answered by the SpaMedica® franchisor trainer to my complete and total satisfaction.

Franchisee Signature __________________________________________________________

Name ________________________________ Date _________________

Franchisor Trainer Signature __________________________________________________

Name ________________________________ Date _________________