S.THEPHARM Co. Ltd

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QTFILL PLUS Training Material

1. Training Objectives & Target Audience

- Master the safe and effective use of HA fillers.
- Build the capability to prevent complications and respond promptly**.**
- Target audience: Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.

2. Product descriptions

- **Model name**
  QTFILL PLUS AQ
  QTFILL PLUS FINE
  QTFILL PLUS DEEP
  QTIFILL PLUS Sub-Q

- **General description**
  This product is a bio-material for tissue restoration. Syringe is filled with 0.3 % Lidocaine hydrochloride with a derivative of cross-linked sodium hyaluronate originated from bacterial fermentation gel. It is intended to be used for facial tissue augmentation for mid- to-deep dermal implantation for the correction of moderate to severe facial wrinkles and Nasolabial folds. The addition of lidocaine provides a pain relieving effect during treatment.

- **Composition**
  Cross-linked Sodium hyaluronic acid: 24 mg
  Lidocaine hydrochloride: 3.0 mg
  Sodium hydroxide: 2.0mg
  Sodium phosphate dibasic: 1.26mg
  Sodium phosphate monobasic dehydrate: 0.46mg
  Sodium chloride: 6.5mg
  Purified water: q.s 1mL

- **Shelf life**
  2 years

- **Storage condition**
  Room temperature(2℃~25℃), avoid light and freezing

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3. Application and Indication of each models

- **QTFILL PLUS AQ** is indicated to be used for superficial dermis injection for correction of fine lines and wrinkles or facial defects.
- **QTFILL PLUS FINE** is indicated to be used for lip defects or volume enhancement.
- **QTFILL PLUS DEEP** is indicated to be used for mid to deep dermis injection for correction of scars or deep wrinkles or facial tissue augmentation.
- **QTFILL PLUS Sub-Q** is intended to be used for a facial tissue augmentation for mid to deep dermal implantation for the correction of moderate to severe facial wrinkles and folds.

4. Method of use

- **Preparatory requirement before use**

1) This product shall be used by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.
2) Before using it the doctor shall provide sufficient explanation to the consumer about indications, contraindications and potential side-effects of this product.
3) Before its use it is necessary to check and see if sterilized condition is damaged or not.
4) Check the effective period on the label of the product

- **Sequence of manipulation and method of use.**

1) Before use, disinfect the part subjected to injection thoroughly.
2) Carry out partial anesthesia when required.
3) Insert needle to injection syringe.
4) A certain amount of this product is injected into skin where the injection is required according to judgement of medical professional and when required repetitive injection may be made.
5) After injection the part where injection is made shall be shaped by tip of hands.
6) Regular additional injection is required or demanded in order to maintain improved condition

- **Method of storage and management after use**

1) Used needles and syringes must be safely disposed in accordance with regional regulations on medical waste.
2) Never resterilize and use it again.

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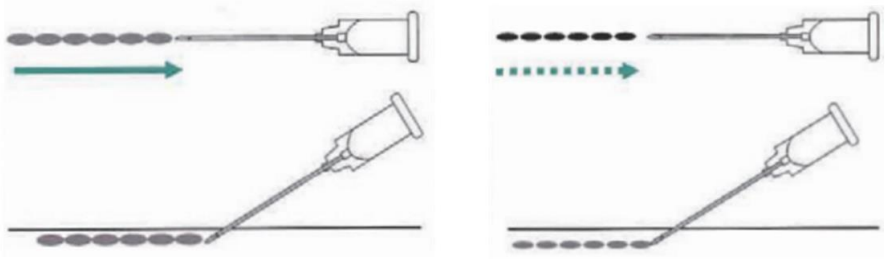
5. Injection Techniques

There are many different techniques for injecting QFTILL PLUS. The most appropriate method should be selected according to the purpose of the injection

- **Retrograde injection technique(Figure A)**
  The practitioner inserts the needle or cannula (a thin tube) into the skin at the target area and advances it to the appropriate depth. The filler is then injected while the needle or cannula is slowly withdrawn. This "retrograde" action – injecting while withdrawing – allows for a more controlled and even distribution of the filler material.

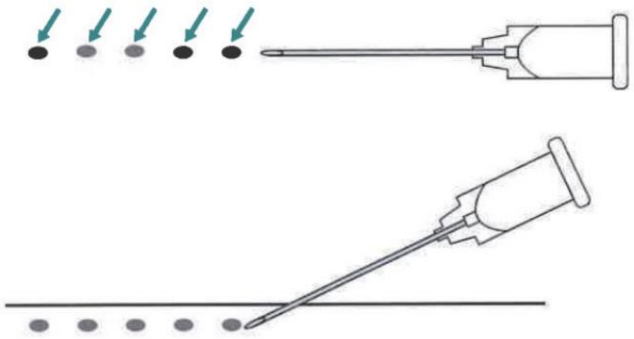
(Figure a. Retrograde injection technique)

- **Linear & serial threading injection technique**
  The linear threading technique involves inserting the needle or cannula at one point of entry and then injecting the filler in a continuous line as the needle is pulled out. This technique is often described as a 'thread' of filler being placed through a linear channel.
  In contrast to linear threading, serial threading (also known as the serial puncture technique) involves multiple small injections along a line or area. Instead of a continuous thread, the filler is deposited in a series of small, separate boluses.



(Figure b. Linear & serial threading injection technique)

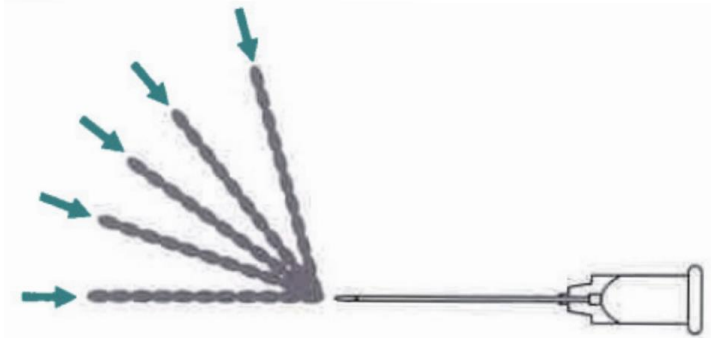
- **Serial puncture injection technique**
  The serial puncture technique involves making multiple, small, individual injections at specific points along the target area. Each injection deposits a small amount of the substance, such as a dermal filler or other injectables.



(Figure c. Serial puncture injection technique)

- **Fanning injection technique**

  The fanning technique involves injecting dermal filler using a series of injections that radiate out from a central point, much like the spread of a fan. This allows for a broad coverage area while minimizing the number of puncture points on the skin.



(Figure d. Fanning injection technique)

6. Warning, Precautions for use, Undesirable side-effect, contraindication, Limitation

- **Warning**

1) Consumers who are hypersensitive to lidocaine or amide-type local anesthetics should not use.
2) Injection to intradermal or upper part of periosteum.
3) Do not resterilize at the time of use.
4) Avoid injecting to blood vessel which is likely to cause occlusion of blood vessels (tissue necrosis due to it).
5) Avoid using by mixing with other products.
6) Do not re-use.
7) Check and see if sterile condition is not damaged before use.
8) Check the effective period on the label of the product.
9) Do not inject into inflammatory or infected skin.
10) Do not use this product in combination with laser procedures, chemical peels, or other exfoliation techniques.
11) This product is used to temporarily improve the facial wrinkles of adults and is prohibited to be used by minors.
12) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or consumer is established.
13) Re-use of the product can degrade performance of the device and may lead to severe cross-infection.

- **Precautions for use**

1) Comply with general precautions at the time of injection to intradermal or upper part of periosteum.
2) Always be careful because danger of infection is intrinsic.
3)There should be sufficient anatomic knowledge on the part where injection is made.
4) Avoid injecting to the part where permanent implant was made.
5) Until disappearance of edema or sense of heat at the part where injection is done, the consumer shall not expose the part where injection is made to sizzling heat or extreme coldness.
6) Avoid use in consumers who expect results beyond the intended effects.

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7) For the case where this product is injected to the part where it is being treated with other filler, there is no verified result.
8) Doing make-up within 12 hours after the injection is prohibited. Long-term exposure to sunlight, UV, gel or sauna (sweating bathroom) is prohibited for 2 weeks after the injection.
9) Severe side-effect such as blindness, etc. may happen in case of injection into blood vessel, and therefore, using it to the eye contours (eye circle or eyelids) where its injection into blood vessel is highly likely is prohibited. Special attention shall be paid at the time of using.
10) There was no established result on safety and effectiveness for the case of using for a long period beyond the time which is established by clinical research.
11) There is no established evidence on the safety and effectiveness of lip broadening.
12) Injection to consumer who has history of herpetic eruption may lead to the recurrence of it.
13) No safety is guaranteed to consumer who tend to develop keloid scarring, hyperpigmentation and hypertrophic scarring.
14) This operation shall be carried out by doctor who is sufficiently trained for such operation.
15) Doctor shall sufficiently explain to consumer about indications, contraindications and potential side-effects before injection.

- **Undesirable side-effect**

1) Users must inform consumers of potential undesirable side effects, which may occur either immediately or after a delay following the injection. These side effects include, but are not limited to:

- Blindness
- Necrosis
- Vascular damage
- Hypersensitivity reaction
- Capsule formation and contracture
- Seroma
- Infection
- Nerve injury
- Compartment pressure problems and compartment syndrome
- Discomfort or pain
- Interruption of wound healing
- Scarring and scar hyperpigmentation and hypertrophy
- Inflammation
- Edema
- Swelling
- Bruising
- Irritation
- Redness
- Hyperpigmentation
- Granuloma
- Regional swelling or lymphadenopathy
- Migration of the device
- Hematoma
- Device visibility through the skin
- Abscess

2) After injection, symptom such as redness, edema, pain, bruising or irritation may appear and it shall disappear for itself after 1~2 weeks.

3) After injection, inflammation accompanied by a wound or pain may persist for approximately one week.

4) After injection, abscess and hypersensitivity reactions may occur, so appropriate precautions should be taken.

The following side-effects were reported in lidocaine injections (for systemic administration)

a. Shock

Symptoms such as shock may be observed. If blood pressure reduction, facial pale, abnormal pulse, respiratory depression, etc are observed, immediately discontinue administration and take appropriate action.

b. Malignant high fever

Severe malignant hyperthermia accompanied by unknown vomiting, arrhythmia, blood pressure fluctuations, rapid temperature rise, muscle stiffness, reddening of blood (cyanosis), hyperventilation, sweating, acidosis, hyperkalemia and myoglobinuria may appear infrequently. If these symptoms are accompanied by malignant hyperthermia during administration of this drug, discontinue administration immediately and take appropriate actions such as intravenous administration of trolene sodium, systemic cooling, hyperoxia to pure oxygen, and correction of acid base equilibrium. In addition, this symptom can lead to kidney failure, so the dose should be kept.

c. CNS(Central nervous system)-related side-effects

- If you have any of these symptoms, take appropriate measures such as diazepam or a short-acting time-consuming barbituric acid (thiopental sodium).
- Drowsiness, anxiety, excitement, ignorance, dizziness, nausea, vomiting, etc. may appear.

Carefully monitor for signs of shock or poisoning symptoms and take appropriate action if necessary.

d. Hypersensitivity

Skin symptoms such as urticaria, edema, etc may appear.

e. Because of the rapid rate at which Lidocaine HCl is metabolized, any condition that affects liver function may alter Lidocaine HCl kinetics. The half-life may be prolonged two-fold or more in consumers with liver dysfunction. Renal dysfunction does not affect Lidocaine HCl kinetics but may increase the accumulation of metabolites.

6) If you experience any of these undesirable side-effects or any other unexpected symptoms after injection that may require medical attention, please promptly report them to the healthcare professional for appropriate medical care and the manufacturer by contacting our contact point below.

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- **Contraindications**

- Consumers who are known to be hypersensitive to hyaluronic acid
- Consumer who showed anaphylaxis to raw materials of filler
- Consumer who has history of serious allergy or anaphylaxis
- Consumer who has bleeding disorder in past or present time
- Consumer who are taking thrombolytic agents or anticoagulants
- Consumer who has received anticoagulants, antiplatelet drugs, vitamin E or NSAISs within 2 weeks
- Consumer who has used topical agents (steroids and retinoid: medicine only, excluding cosmetics) on the facial

region within one month
- Consumer who has had experience in being subject to calcium hydroxyapatite (CaHA) around the nasolabial folds or have got filler infections such as collagen, or hyaluronic acid(HA)
- Consumer who has received acne procedures, dermabrasion, skin resurfacing, wrinkle correction or cosmetic procedure (e.g. face-lifting, etc.) on the facial region within the past 6 months
- Consumers who use cosmetic product to correct winkles within six months
- Consumer who has a history of autoimmune disorder or who have received immunotherapy
- Consumer with a history of streptococcal infections on the facial region
- Consumer with inflammatory and/or infectious disease
- Consumers who are hypersensitive to lidocaine or amide-type local anesthetics
- Due to the potential systemic absorption of lidocaine, particularly with repeated administration, the product is contraindicated in individuals with:
• History of seizures or convulsions following lidocaine administration.
• Grade II–III atrioventricular (AV) block
• Impaired intraventricular conduction
• Adams-Stokes syndrome
• Severe bradycardia or sick sinus syndrome
• Significant reduction in left ventricular function
• Severe hepatic impairment

- **Limitation**

The device is restricted for use by the following consumers:
- Consumers under age of 21
- Consumers who are pregnant or breastfeeding
- Consumers who are prone to hypertrophic scarring

7. Management of the most common side-effects

The following table outlines commonly observed side-effects and general recommendations for their management. Consumers must be advised to seek medical attention from a medical professional in all cases where symptoms persist or worsen.

Side-effects	Description	Recommended Action
Overdosing	Excess volume leading to unnatural appearance or asymmetry	May be managed by gentle massage immediately after injection. In some cases, enzymatic degradation using hyaluronidase may be considered by a trained medical professional. Consultation with a physician is essential.
Swelling	Localized or diffuse swelling at the injection site	Apply cold compress intermittently for the first 24 hours. Avoid strenuous activity and alcohol. Persistent or severe swelling should be evaluated by a healthcare provider.
Hardening	Formation of firm areas or	May resolve spontaneously. Gentle massage may be applied

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Side-effects	Description	Recommended Action
	lumps under the skin	if recommended by a healthcare professional. In case of persistence, nodules should be evaluated and managed by a physician, potentially with hyaluronidase or corticosteroid therapy.
Nodules	Delayed or immediate onset of localized nodular reactions	Immediate nodules: conservative management or hyaluronidase. Delayed onset: may require corticosteroids, antibiotics, or anti-inflammatory treatment under medical supervision. Referral to a dermatologist or experienced clinician is recommended.
Immune responses	Redness, warmth, itching, or delayed swelling possibly due to immune response	Discontinue further injections. Antihistamines, corticosteroids, or other immunomodulating therapies may be indicated depending on severity. All reactions must be assessed and treated by a qualified healthcare professional. Emergency care should be sought in the case of anaphylaxis.