



# **PERFECTHA® DERM**

## **Product Specifications**

**1-844-226-8277**

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**CONTENTS OF THE CARTON**

- 1 single-use syringe with 1ml cross-linked hyaluronic acid gel at a concentration of 20mg/ml in phosphate-buffered saline. The contents of the syringe have been steam-sterilised (CE 2195).
- 2 single-use 30G x 13mm needles, sterilised by radiation (CE 0123)\*.
- 1 two-part tracking label for the patient and for the healthcare professional (to be attached to the patient's records)

**INTENDED USE**

PERFECTHA is a line of resorbable hyaluronic acid (HA) gel implants intended for reconstructive purposes in the treatment, for instance, of facial lipoatrophy, or morphological asymmetry associated with the aging process or other underlying conditions. PERFECTHA is for intradermal and subcutaneous application and is implanted in the areas of the face and hands to fill skin depressions and also for the augmentation of tissue volume.

PERFECTHA DERM is an injectable implant for superficial subcutaneous injection. It is indicated for the filling of medium lines and depressions, such as nasolabial folds and marionette lines, for lip enhancement and scars.

**PRODUCT DESCRIPTION**

The device is intended to be used by registered healthcare professionals and intended to be used in adult patients (over 18) whom are not pregnant or breast-feeding and are deemed appropriate for treatment by the healthcare professional.

PERFECTHA DERM is a sterile cross-linked hyaluronic acid gel of non-animal origin. The gel is supplied in a pre-filled, ready-to-use, single-use syringe.

With PERFECTHA implants, it is possible to fill lines and restore volume to the face via the action of hyaluronic acid, which has the ability to bind to water. These are "passive" products, the main effect of which is achieved without any biological or pharmacological action. Their filling effect is a function of the quantity of implant injected; the maximum recommended dose must however not be exceeded. Effects are immediately apparent; how long they last depends on the volume and depth of injection, the healthcare professional's injection technique and the patient's lifestyle. PERFECTHA DERM is biodegradable and is broken down by the metabolic pathways of hyaluronic acid already present in the body. PERFECTHA is an implantable dermal filler. Treatment effects have variable duration\*\* dependant on the product variant used, medical practitioner injection technique, patient lifestyle and metabolic rate.

\*\*studies have shown effects from 6-18 months dependant on product variant.

Before the first session, contact your local Sinclair representative or authorised PERFECTHA distributor for additional information on injection techniques and training opportunities.

**PRECAUTIONS FOR USE**

- This product may be administered only by a registered healthcare professional in accordance with local regulations.
- This device is designed to be injected into the superficial subcutaneous layer by a healthcare professional who has been specifically trained in injection techniques for cosmetic filler procedures. The healthcare professional's technical competence is crucial to the success of the treatment.
- All injections carry a risk of infection, aseptic techniques and standard practices should be employed to avoid contamination and infection.
- Knowledge of the anatomy of the site to be treated and specific precautions are essential in order to avoid perforation or compression of vessels, nerves and other more fragile structures.
- Use of the supplied needle is recommended. The design, diameter and length have been validated for optimum use with the injection.
- It is also possible to use injection accessories presented in the table on the back page of this leaflet. The maximum recommended lengths of needles and cannulas covering a range of gauge sizes are included. The design, diameter and length have been validated for effective

use with the injection. (\*\*\*)The needle information in the table is not applicable to Terumo regular walled needles, which are not recommended for use with PERFECTHA products).

- The needle and cannula recommendations are based solely on extrusion testing and clinical judgement should be used to determine the gauge and length most suitable for the application area/depth of treatment.
- Use of injection equipment other than that recommended in the table of alternatives increases the risk of the accessory and/or the Luer lock fitting becoming detached.
- There is known incompatibility between hyaluronic acid and quaternary ammonium salts such as benzalkonium chloride (precipitation of hyaluronic acid). Therefore PERFECTHA DERM should never come into contact with such products or with medical or surgical equipment treated with this type of product. The healthcare professional should check the composition of the disinfectant used to clean the patient's skin prior to the injection and exclude the use of products containing such substances.
- Avoid injection in patients with clotting disorders or taking thrombolytics, anticoagulants, aspirin, non-steroidal anti-inflammatory drugs or vitamin C. These can predispose to swelling reactions at the injection site and can increase bleeding and the risk of bruising after the injection. These substances should be temporarily discontinued at least 7 to 10 days before the injection, and only with medical clearance with prescribed anticoagulants such as warfarin or clopidogrel bisulfate.
- The maximum recommended dose of PERFECTHA DERM gel is no more than 30ml per 60kg bodyweight per full course of treatment without prior anaesthesia, and should not exceed 60ml per 60kg bodyweight per year.
- The patient should be advised not to apply make-up for 24 hours following the injection and to avoid prolonged exposure to UV rays, temperatures below 0°C, saunas and Turkish baths for 2 to 3 weeks following the injection.
- Take extra care when injecting into the nose or lips as these are high risk, sensitive areas more prone to developing adverse events.

## CONTRAINDICATIONS

- Do not mix with other products before injection. This can alter the functionality of the product and affect the sterility of the gel leading to an increased risk of infection.
- Do not inject into the periorbital region (eyelids, under-eye dark circles, crow's feet, tear trough) or glabella region as there is risk of ocular ischaemic events leading to loss of vision.
- Do not inject via the intramuscular or intravascular route. Risk of vascular compression events, which can manifest as discolouration, necrosis or ulceration at the implant site or in the area supplied by the affected blood vessels; risk of ischaemic events in other organs as a result of embolism. In the event of superficial discolouration or blanching of the skin, the injection must be stopped immediately and the area massaged until its normal colour is restored.
- Do not over-correct.
- Avoid injections in patients with known hypersensitivities to avian proteins, feathers and egg products, as patients with known hypersensitivities to these items may also be sensitive to sodium hyaluronate.
- Do not use in patients:
  - with epilepsy which is not controlled by treatment
  - with tendency to develop hypertrophic scars
  - with known hypersensitivity to hyaluronic acid
  - with porphyria
  - with active (or a history of) autoimmune disease
  - with a history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement)
  - with areas affected by inflammatory and/or infectious skin problems (acne, herpes etc.) or tumours at or near the treatment site
  - undergoing laser or UV treatment, deep chemical peel, dermabrasion or prolonged sun exposure. Following a superficial peel, injection is not recommended if the inflammatory

- reaction induced by the peel is significant and/or still visible
  - receiving medical treatment that reduces or inhibits liver metabolism (cimetidine, beta blockers)
  - that are pregnant or breastfeeding women, children
- Do not use on areas previously treated with fillers of animal origin, permanent implants or implants containing a substance other than hyaluronic acid. Risk of incompatibility between products; risk of activation or reactivation of the immune system and/or latent infections.

## INSTRUCTIONS FOR USE

1. Before starting treatment, the healthcare professional must obtain information about the patient's history and state of health. The healthcare professional must examine the compatibility of the patient, the chosen treatment and the anatomical area to be treated; in particular, it is recommended that double testing or preventive treatment are offered before any injection. The healthcare professional must adhere strictly to the conditions of use for which the device is intended. The healthcare professional must inform the patient about the indications, contraindications, incompatibilities, side effects and undesirable effects of the device.
2. Assemble the Syringe ready for injection:
  - a. Holding the syringe upright on the ribbed part of the Luer lock, tilt the white cap to break seals (Fig 1).
  - b. Remove the syringe cap in a straight upward direction (Fig 2).
  - c. Unscrew cap from the needle/ cannula casing. Holding the Luer Lock firmly in a fixed position, screw the desired needle/ cannula into the Luer lock of the syringe by rotating the needle/ cannula (Fig 3).
  - d. Remove needle/ cannula casing.
3. Before starting the injection, expel all the air from the needle/ cannula by pushing on the plunger until a drop of gel appears at the tip of the needle/ cannula.
4. The patient should be seated at an angle of at least 45° in order to prevent the face from becoming distorted, which increases the risk of "imprecise treatment".
5. Marking the area to be treated should help guarantee the precision of the injection. The area to be treated should first be cleaned and disinfected with an appropriate antiseptic solution. Local or regional anaesthetic block may be used depending on patient/ healthcare professional preference.
6. The quantity to be injected depends on the area to be corrected. Do not inject more than 3.0ml per treatment site during each session.
7. Inject the product slowly; injection of one 1ml syringe takes between 4 to 5 minutes.  
A low injection speed may help to prevent the detachment of accessories during injection and to reduce the occurrence of local adverse events after injection.
8. If the needle/ cannula becomes blocked, do not increase the pressure on the plunger rod; stop the injection and replace the needle/ cannula. A bubble in the syringe barrel does not constitute a known risk during administration.
9. Administration must be halted just before withdrawing the needle/ cannula in order to prevent spillage of the product at the administration site.
10. As the results are immediate, the quantity administered must correct the defect without producing over-correction.
11. The treated area should be massaged gently to ensure the implant is well distributed.
12. Application of ice packs to the treated area for several minutes is recommended in order to minimise swelling.
13. Dispose of syringe and needle/ cannula as contaminated clinical waste.

## SIDE EFFECTS

- Accidental injection into terminal vessels or vascular compression caused by implantation of an injectable product may lead to vascular occlusion, with consequences such as ischaemia/necrosis.
- Damage to blood vessels may cause significant bruising and, in the most severe cases, lead to varicose veins.

- Involvement of nerves may cause persistent pain, itching and, in the most severe cases, transient paraesthesia.
- Too deep an injection or intramuscular injection may result in increased consumption of hyaluronic acid and hence shorten the duration of effect of the implant.
- Too superficial an injection may cause colouration or discolouration of the area around the injection site and/or formation of palpable nodules.
- Failure to observe the rules of hygiene for injection and the manufacturer's warnings may lead to the development of an infection.
- There is a potential for an increased risk of post-inflammatory hyperpigmentation in people of darker skin colour.
- In rare cases, severe allergic reaction (anaphylactic shock) that requires immediate emergency medical assistance can occur.
- Migration/movement of filler material at injection site or through the skin could occur which may result in tissue reaction or infection.
- Undesirable immediate/delayed onset effects include (non-exhaustive list):
  - inflammatory reactions (redness, swelling, rash, oedema, erythema etc.)
  - bruising
  - itching
  - tenderness
  - induration/nodules/papules/lump/fistula/granuloma
  - discolouration
  - pain/tenderness
  - hypersensitivity
  - acne
  - atrophy/scarring
  - blisters
  - dermatitis
  - herpes reactivation
  - ecchymosis

Most symptoms usually resolve within 1 to 2 weeks after the injection. If these effects persist beyond 2 weeks or if any other side effects appear, the patient must tell his/her healthcare professional as soon as possible. The healthcare professional should manage these with appropriate treatment.

- Very rare reactions include (non-exhaustive list):
  - infection
  - neurological symptoms such as paraesthesia
  - abscess
  - implant migration
  - visual disturbance
  - ischaemia/necrosis
  - ocular ischaemia leading to vision loss

The onset of these undesirable effects or any other side effects must be reported immediately. Please contact the local Sinclair representative or authorised PERFECTHA distributor. Alternatively send the details to Sinclair on: [quality@sinclairpharma.com](mailto:quality@sinclairpharma.com)

## **WARNINGS**

- Do not freeze ( $<2^{\circ}\text{C}$ ) for risk of implant degradation.
- Check the integrity of the packaging, product and needles provided; do not use the device if the packaging is damaged or open.
- Check the expiry dates stated on the labelling; do not use the device if the expiry date has passed.
- Do not re-sterilise as the product quality cannot be guaranteed following additional processing.
- Do not reuse: PERFECTHA DERM is for single use. The syringe, needle/ cannula used, and any remaining product must be discarded in suitable containers after use. The reuse of disposable single-use syringes and needles/ cannulas exposes the public to serious risks of

infection. Reuse of any residual product can result in an increase in known undesirable effects.

- Never attempt to straighten a bent needle/ cannula; they must be discarded in suitable containers and replaced.

The expiry date of the product is stated on the packaging.

Store between 2°C and 30°C, protect from frost and sunlight.

If you have any complaints then please contact [quality@sinclairpharma.com](mailto:quality@sinclairpharma.com)



Caution  
Attention  
Precaución  
Upozornění  
تنبيه  
주의  
警告  
注意  
ข้อควรระวัง  
Thận trọng  
Perhatian  
Осторожно  
Увага  
Attenzione  
Atenção  
Sicherheitshinweis  
Waarschuwing  
Försiktighet  
Advarsel  
Προσοχή  
Dikkat  
Uprozornienie  
Внимание  
Ateňtie  
Oppez  
Figyelem  
Svarilo



Manufacturer  
Fabricant  
Responsable de la  
fabricación  
Výrobce  
المصنع  
제조업체  
生産商  
製造者  
ผู้ผลิต  
Nhà sản xuất  
Produsen  
Изготовитель  
Vyrобник  
Produttore  
Fabricante  
Hersteller  
Fabrikant  
Tillverkare  
Producuent  
Παρασκευαστής  
Üretici  
Výrobca  
Производитель  
Fabricantul  
Proizvodáč  
Gyártó  
Proizvajalec



Temperature Limit  
Limites de température  
Límite de temperatura  
Teplotní meze  
حد درجة الحرارة  
온도 제한  
应用温度范围  
使用温度範圍  
ขีดจำกัดอุณหภูมิ  
Giới hạn Nhiệt độ  
Batas Suhu  
Температура хранения  
Температура зберігання  
Limite di temperatura  
Limite de temperatura  
Temperaturbegrenzung  
Temperaturgrens  
Temperaturgräns  
Temperaturgrænse  
Όριο θερμοκρασίας  
Sıcaklık Sınırı  
Limit teploty  
Температурна граница  
Limita de temperatură  
Temperaturno ograničenje  
Hőmérsékleti korlátozás  
Temperaturna omejitve



Do not resterilise  
Ne par restériliser  
No reesterilizar  
No reesterilizujte  
لا تعيد تعقيم  
재멸균 금지  
不可重新消毒  
再滅菌禁止  
ห้ามนำไปฆ่าเชื้อซ้ำ  
Không tiệt trùng lại  
Jangan disterilkan ulang  
Не стерилизовать повторно  
Не стерилизувати повторно  
Non risterilizzare  
Não voltar a esterilizar  
Nicht erneut sterilisieren  
Niet opnieuw steriliseren  
Får inte omsteriliseras  
Må ikke reesteriliseres  
Μην επαναποστεριώνετε  
Yeniden sterilize etmeyin  
Nesterilizujte opakovane  
Da ne se sterilizira повторно  
A nu se resteriliza  
Ne sterilizirati ponovno  
Tilos újrateilizálni  
Ne sterilizirajte ponovno



Keep away from sunlight  
Conserver à l'abri du soleil  
Mantener lejos de la luz solar  
Chraňte před působením slunečního záření  
يُحفظ بعيداً عن ضوء الشمس  
직사광선 노출 금지  
避免日光照射  
日光の当たる場所に保管しないでください  
เก็บให้ห่างจากแสงอาทิตย์  
Tránh ánh nắng mặt trời  
Jauhkan dari sinar matahari  
Хранить вдали от воздействия солнечного света  
Зберігати якнайдалі від прямих сонячних променів  
Tenere lontano dalla luce solare  
Manter afastado da luz solar  
Vor Sonnenlicht schützen  
Uit het zonlicht houden  
Ljuskänsligt  
Må ikke opbevares i sollys  
Φυλάσσεται μακριά από το ηλιακό φως  
Güneş ışığından uzak tutun  
Chraňte pred slnečným žiarením  
Да се пази от слънчева светлина  
A se feri de lumina solară  
Držite podalje od sunčeve svjetlosti  
Napfénytől védve tárolandó  
Zaščitite pred sončno svetlobo



Batch code  
Número de lot  
Código de lote  
Kód šarže  
كود الشحنة  
배치 코드  
批号  
バッチコード  
รหัสเบตซ์  
Mã lô hàng  
Kod batch  
Kod partii  
Kod partii  
Codice lotto  
Lote  
Chargenbezeichnung  
Partijcode  
Sats  
Batchkode  
Κωδικός παρτίδας  
Parti Kodu  
Kód šarže  
Kod na partiidata  
Codul lotului  
Serijski broj  
Tételkód  
Oznaka serije



Date of Manufacture  
Date de fabrication  
Fecha de fabricación  
Datum výroby  
تاريخ التصنيع  
제조 일자  
生产日期  
製造日  
วันที่ผลิต  
Ngày Sản xuất  
Tanggal Pembuatan  
Дата изготовления  
Дата виробництва  
Data di fabbricazione  
Data de fabricație  
Herstellungsdatum  
Productiedatum  
Tillverkningsdatum  
Produktionsdato  
Ημερομηνία παρασκευής  
Üretim Tarihi  
Datum výroby  
Дата на производство  
Data fabricației  
Datum proizvodnje  
Gyártás dátuma  
Datum izdelave



Sterilised using steam  
Stérilisé à la vapeur  
Esterilizado por vapor  
Sterilizováno parou  
مُعقم بالبخار  
증기 멸균  
蒸汽灭菌  
蒸気滅菌  
ผ่านการฆ่าเชื้อด้วยไอน้ำ  
Tiệt trùng bằng hơi nước  
Disterilkan menggunakan uap  
Стерилизация паром  
Стерилизація паром  
Sterilizzato in autoclave  
Esterilizado a vapor  
Steril mit Dampf  
Gesteriliseerd met stoom  
Steriliserad med ånga  
Steriliseret med damp  
Αποστειρωμένο με χρήση ατμού  
Buhar ile sterilize edilmıştır  
Sterilizované pomocou pary  
Стерилизира се с помощта на пара  
Sterilizat cu abur  
Sterilizirano parom  
Gőzzel sterilizálva  
Sterilizirano s paro



Medical Device  
Dispositif médical  
Producto sanitario  
Medicinský prostředek  
جهاز طبي  
의료 기기  
医疗器械  
醫療器具  
อุปกรณ์ทางการแพทย์  
Thiết bị Y tế  
Alat Kesehatan  
Μεδικινησκόπιο  
Медицинское изделие  
Медицинський виріб  
Dispositivo medico  
Dispositivo médico  
Medizinprodukt  
Medisch hulpmiddel  
Medicinteknisk produkt  
Medicinsk udstyr  
Ιατροτεχνολογικό προϊόν  
Tibbi Cihaz  
Zdravotnícka pomôcka  
Μεδικινησκόπιο  
Dispozitiv medical  
Medicinski proizvod  
Orvosi eszköz  
Medicinski pripomoček



Consult Instructions for Use  
Consulter la notice d'utilisation  
Consultar las instrucciones de uso  
Viz návod k použití  
راجع إرشادات الاستخدام  
사용 설명서 참조  
查阅使用说明书  
使用方法を参照してください  
ศึกษาวิธีใช้  
Tham khảo Hướng dẫn Sử dụng  
Baca Petunjuk Penggunaan  
Обратитесь к инструкции по применению  
Зверніться до інструкції із застосування  
Consultare le istruzioni per l'uso  
Consultar as Instruções de Utilização  
Informationen beachten  
Raadpleeg de instructies voor gebruik  
Läs bruksanvisningen  
Se bruksanvisningen  
Συμβουλευτείτε τις οδηγίες χρήσης  
Kullanma Talimatlarını Bakın  
Pozrite si návod na používanie  
Направете справка в Указанията за употреба  
Consultati instrucțiunile de utilizare  
Pogledati u uputama za uporabu  
Olvassa el a használati útmutatót  
Glejte navodila za uporabo



Use-by Date  
Date limite d'utilisation  
Fecha de caducidad  
Datum spotřebny  
التاريخ الذي يُستعمل قبله  
사용 기한  
有效期  
使用期限  
วันหมดอายุ  
Sử dụng đến ngày  
Gunakan hingga Tanggal  
Срок годности  
Термін придатності  
Utilizzare entro  
Utilizar até  
Verfalldatum  
Uiterste gebruiksdatum  
Utgångsdatum  
Anvendes før  
Ημερομηνία λήξης  
Son Kullanma Tarihi  
Datum spotreby  
Используйте до  
Data expirării  
Datum isteka uporabe  
Felhasználhatóság dátuma  
Datum izteka roka uporabnosti



Serial number  
Número de série  
Número de serie  
Sériové číslo  
الرقم التسلسلي  
일련번호  
序列号  
シリアル番号  
หมายเลขผลิตภัณฑ์  
Ső ső-r  
Nomor seri  
Серийный номер  
Серійний номер  
Número di serie  
Número de série  
Seriennummer  
Seriennummer  
Seriennummer  
Σειριακός αριθμός  
Seri numarası  
Sériové číslo  
Серієм номер  
Număr de serie  
Serijski broj  
Sorozatszám  
Serijška številka



Sterilised using irradiation  
Stérilisé par irradiation  
Esterilizado por radiación  
Sterilizováno ozářením  
مُعقم بالإشعاع  
방사선 멸균  
辐照灭菌  
放射線滅菌  
ผ่านการฆ่าเชื้อด้วยการฉายรังสี  
Tiệt trùng bằng chiếu xạ  
Disterilkan menggunakan iradiasi  
Радіаційна стерилизація  
Sterilizzato mediante irradiazione  
Esterilizado por radiación  
Steril durch Bestrahlung  
Gesteriliseerd met straling  
Steriliserad med strålning  
Steriliseret med stråling  
Αποστειρωμένο δια ακτινοβολίας  
İşinlame ile sterilize edilmiştir  
Sterilizované pomocou ožarovania  
Стерилизира се с помощта на радиация  
Sterilizat prin iradiere  
Sterilizirano zračenjem  
Besugárzással sterilizálva  
Sterilizirano z obsevanjem



Do not re-use  
Ne pas réutiliser  
No reutilizar  
Ne použivajte opakovaně  
لا تعيد استعماله  
재사용 금지  
不可重复使用  
再使用禁止  
ห้ามใช้ซ้ำ  
Không tái sử dụng  
Jangan gunakan kembali  
Не використовувати повторно  
Не використовувати повторно  
Non riutilizzare  
Não reutilizar  
Nicht zur Wiederverwendung  
Niet hergebruiken  
Får inte återanvändas  
Må ikke genbruges  
Μην επαναχρησιμοποιείτε  
Yeniden Kullanmayın  
Ne použivajte opakovane  
Da ne se izpolzava повторно  
A nu se reutiliza  
Ne koristite ponovno  
Tilos újrafelhasználni  
Samo za enkratno uporabo

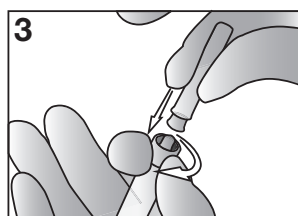
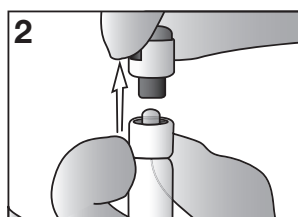
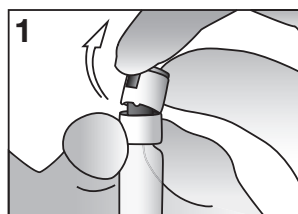


Do not use if package is damaged  
Ne pas utiliser si l'emballage est endommagé  
No utilizar si el envase está dañado  
Ne použivajte, je-li obal poškozený  
لا تستعمل المنتج إذا كانت العبوة تالفة  
포장이 손상된 경우 사용 금지  
如包装损坏，不可使用  
パッケージ破損の際は使用しないでください  
ห้ามใช้หากบรรจุภัณฑ์เสียหาย  
Không sử dụng nếu bao bì bị hỏng  
Jangan gunakan jika kemasan rusak  
Не використовувати при пошкодженні упаковок  
Не застосовувати в разі пошкодження упаковок  
Non usare se la confezione è danneggiata  
Não utilizar se a embalagem estiver danificada  
Bei beschädigter Packung nicht verwenden  
Niet gebruiken als de verpakking beschadigd is  
Får inte användas om förpackningen är skadad  
Må ikke genbruges, hvis emballagen er beskadiget  
Μη χρησιμοποιήσετε αν η συσκευασία έχει υποστεί ζημιά  
Kullanma talimatları hasarlı ise kullanmayın  
Ne použivajte, ak je obal poškodený  
Не використовуйте, ако опаковка є пошкоджена  
A nu se utiliza dacă ambalajul este deteriorat  
Nemojte koristiti ako je pakiranje oštećeno  
Ne használja fel, ha a csomagolás sérült  
Ne uporabljajte, če je embalaža poškodovana



| Ingredients                 | Quantity (w/w%) |
|-----------------------------|-----------------|
| Sodium Hyaluronate          | 2.0             |
| Sodium Chloride             | 0.9             |
| Sodium dihydrogen phosphate | 0.0187          |
| Disodium Phosphate          | 0.0374          |
| Water for Injections        | q.s to 100%     |

| Gauge            | Maximum Length |
|------------------|----------------|
| <b>Needle***</b> |                |
| 21-22 G          | 50 mm          |
| 25 G             | 25 mm          |
| 27-30 G          | 13 mm          |
| <b>Cannula</b>   |                |
| 21-27G           | 50 mm          |



\* For Needles:  
 Legal Manufacturer – TSK  
 Laboratory, Japan; CE 0123  
 EC-Representative: Emergo  
 Europe, Molenstraat 15,  
 2513 BH The Hague (NL)



MADE IN FRANCE

[www.perfectha.com](http://www.perfectha.com)

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 Dardilly – France

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