MINI WELL and MINI WELL PROXA

Pre-loaded foldable UV-filtering extended depth of focus aspheric intraocular lenses (IOLs) for mini-incision

Description
MINI WELL (Wavefront Engineering Leading Lens) and MINI WELL PROXA IOLs are progressive extended depth of focus (EDF) IOLs, intended to be implanted in the posterior chamber, more precisely in the capsular bag, to replace the natural crystalline lens for surgical correction of aphakia and presbyopia in adult patients.
MINI WELL and MINI WELL PROXA IOLs are pre-loaded, come in a single-piece design and are intended for mini-incision. These surgical implants are made of a hydrophilic-hydrophobic copolymer with a UV-filtering chromophore (Fig. A, Transmittance Curve), and a refractive index of 1.46 at 35°C. The anterior surface of MINI WELL and MINI WELL PROXA IOLs is based on a patented proprietary optics that provides an extended depth of focus so to have a good progressive vision at all distances. The anterior surface of MINI WELL and MINI WELL PROXA is aspheric. The posterior surface has a double square edge conceived with the aim to prevent the incidence of posterior capsule opacification. The MINI WELL and MINI WELL PROXA IOLs have a biconvex optic shape across the whole diopter range.

Technical characteristics

	Diameter of optic surface (mm) $Ø_P$	Total diameter (mm) $Ø_T$	Vaulting	Number of loops	Power Min. (D)	Power Max. (D)	Diopter increment (D)	Diopter increment (D)	Equivalent additional power (D)
MINI WELL	6	10,75	5°	4	0	+30	0,5 from +10,5 to +30	1 from 0 to +10	+3

	Diameter of optic surface (mm) $Ø_P$	Total diameter (mm) $Ø_T$	Vaulting	Number of loops	Power Min. (D)	Power Max. (D)	Diopter increment (D)	Diopter increment (D)	Equivalent additional Power (D)
MINI WELL PROXA	6	10,75	5°	4	0	+30	0,5 from +10,5 to +30	1 from 0 to +10	+3,25

IOL model, diopter power, suggested A-constant and main dimensions (diameter of optic surface, total diameter, vaulting) are reported on the case and the primary and secondary packagings.

Device material
MINI WELL and MINI WELL PROXA IOLs are made of a hydrophilic – hydrophobic copolymer composed of HEMA (about 70%), EOEMA (about 30%), UV absorber and cross-linker (<0.5%).
These devices are supplied in hydrated state, dipped in sterile and apyrogenic saline solution (0.9% NaCl).
The part of the injector supplied in direct contact with the patient's eye - injector tip - consists of coated medical grade Polyamide.

Sterilization and packaging
MINI WELL and MINI WELL PROXA IOLs are supplied hydrated. The package consists of a double sterile barrier film. The primary package of this IOL consists of a plastic container sealed by an aluminum foil containing a specific loading chamber where the IOL is inserted. The plastic container is filled with a sterile and apyrogenic saline solution. The plastic container is packaged in turn in a pouch. Both are sterilized by steam sterilization.
The primary package of the injector consists of a Tyvek blister. The injector and the blister are sterilized by ethylene oxide sterilization.
The case representing the SKU contains the lens and its injector, the "Product Information" leaflet, the implant card and the labels with the lens ID information.

Indications
The MINI WELL and MINI WELL PROXA intraocular lenses are intended for primary implantation for visual correction of aphakia in adult patients (> 18 years old) with or without presbyopia after removal of a cataractous lens and of aphakia after refractive lensectomy in presbyopic adults who desire increased spectacle independence for distance and near vision. These implants must be positioned within the capsular bag.

Intended clinical benefit
The use of MINI WELL and MINI WELL PROXA intraocular lenses will lead to the benefit of human crystalline lens replacement in patients undergoing cataract surgery or refractive lensectomy for visual correction of aphakia. Furthermore, the optical profile of these IOLs will also allow the treatment of the presbyopia condition restoring patient vision in a range of distances from far to near.

Combined use of the devices
MINI WELL and MINI WELL PROXA intraocular lenses have been designed to be used also in combined bilateral implant condition.
The combined implant of MINI WELL and MINI WELL PROXA allows to obtain a unique system based on the complementary optical design of the two lens models.

Intended user
The MINI WELL and MINI WELL PROXA intraocular lenses are intended for use by ophthalmic surgeons.

Patient information
Before surgery, each patient must receive all information about the implant. The surgeon performing the intraocular lens implantation, must inform the patient of any warning, precaution or adverse event related to the medical device.

Precautions for use
1. In patients who have undergone implantation of the MINI WELL and MINI WELL PROXA intraocular lenses, the auto-refractometer values may not correspond to the actual post-operative refractive value; it is therefore advisable to check the aforementioned values with the subjective examination, through the "fogging" technique.
2. The recent use of contact lenses affects the patient's refraction; therefore, in those wearing contact lenses, surgeons must define corneal stability without contact lenses before determining the power of the intraocular lens.
3. Do not re-sterilise the intraocular lens.
4. Do not reuse the intraocular lens; reuse compromises the sterility of the implant.
5. Do not use the system if the package is damaged or open.
6. Do not use after the expiration date printed on the package.
7. Do not use balanced saline solutions, Ringer lactate and/or hydroxypropyl methylcellulose during the loading procedures of the lens into the injector.
8. Improper handling of the preloaded system as well as improper bending techniques may cause damage to the haptics and/or the optical part of the lens. The surgeon must not attempt to implant lenses with a damaged optical plane or haptics. For a correct handling of the medical device follow the instructions for use being provided.
9. The intraocular lens implant requires adequate surgical skills.
10. Opening the protective packaging requires immediate use of the intraocular lens to prevent contamination or dehydration.
11. The MINI WELL and MINI WELL PROXA intraocular lenses must be kept at room temperature. It is recommended to implant them after keeping them at least 60 minutes at the temperature of the operating room. In this way it is possible to avoid that the thermal shock, resulting from an abrupt exposure to body temperature, causes a transient loss of transparency of the device.

Storage conditions/Transport conditions
Store at temperatures between +5°C – +25°C. During transport, non-prolonged exposure of the product to temperatures higher than those suggested for the storage (up to a maximum of + 45 °C) does not compromise the characteristics of the product.

Warnings
Physicians considering a lens implant in one of the following circumstances should evaluate the potential risks/benefits ratio:
1. Patients with one or more of the following conditions could not be eligible candidates for implantation of a progressive intraocular lens, as it can worsen the pre-existing condition, interfere with diagnosis or the treatment of a condition or potentially be a risk for the patient's sight:
   a. zonular laxity
   b. irregularity and decentration of capsulorhexis
   c. recurrent inflammation of anterior or posterior segment of unknown etiology (chronic uveitis)
   d. patients in whom the intraocular lens might interfere with the ability to observe, diagnose or treat posterior segment conditions
   e. intraoperative challenges which could increase the risk of complications, such as severe bleeding, significant iris damage, uncontrollable elevated intraocular pressure or significant vitreous loss
   f. lack of capsular support for implantation of the intraocular lens in the capsular bag
   g. decompensated glaucoma
   h. dystrophy of corneal endothelium
   i. proliferative diabetic retinopathy
   j. microphtalmus
   k. pediatric patients
   l. suspected microbial infection
   m. patients without an adequate support for the lens from the posterior chamber or the zonule
   n. bilateral congenital cataracts
   o. history of retinal detachment or susceptibility to this condition
   p. monocular patients
2. MINI WELL and MINI WELL PROXA IOLs must be positioned within the capsular bag and not in the ciliary sulcus.
3. Carefully remove all viscoelastic material from the capsular bag. Residues not removed could lead to IOL opacification and increase in intraocular pressure.
4. Choice of type of IOL to be used as well as the implantation method to be adopted (monolateral, bilateral or combined) must be evaluated case by case by the physician according to the clinical need of the patient.
5. Other potential complications following IOL implantation are correlated to cataract surgery.

Adverse events
The potential adverse events that may occur during or after cataract surgery with implantation of an intraocular lens may include:

General adverse events for intraocular lenses
1. Residual refractive error
2. Increase of intraocular pressure
3. Corneal oedema
4. Inflammation (Endophthalmitis, Hypopyon, Cystoid macular oedema)
5. Pupillary block
6. Retinal detachment
7. Displacement of the intraocular lens (Tilt and decentralisation)
8. Secondary surgical intervention (including repositioning of the implant, removal and replacement, PCO, or other surgical procedure)

Adverse events for MINI WELL and MINI WELL PROXA intraocular lenses
1. Increased visual disorders related to the optical characteristics of the intraocular lens:
   a. Reduction of contrast sensitivity
   b. Light artefacts (halos, glare or starbursts)

Instructions for use
The following instructions apply to models of intraocular lenses MINI WELL and MINI WELL PROXA.
1. Appropriate implant selection
   a. Examine the label of the complete package to verify the model, dioptric power or spherical equivalent, design and date of expiration of the product.
   b. Suggested constant A: the constant A on the package is intended as a guideline and starting point for calculating the dioptric power of the implant. We suggest that surgeons should develop the constant value based on their clinical experience.
2. Removing the implant from its package
   a. After opening the case, check that the information on it corresponds to that listed on the label in the lens package.
   b. Open the lens external package and transfer the lens container in the sterile field in accordance with good practices in sterile field management.
   c. Open the injector blister and place it on the sterile operating table.
   d. Carefully open the lens container and remove the loading chamber in which it is lodged.
   e. Insert the loading chamber holding the IOL into the specific injector slot (Fig. 1).
   f. Apply viscoelastic solution first through the front hole until the tip is filled (Fig. 2) and then through the rear hole towards the back of the chamber (Fig. 3) until the solution comes out, in order to obtain a barrier between lens and silicone cushion.
   g. In addition, apply a drop of viscoelastic solution on the tip of the silicone cushion (Fig. 4). It is recommended to use the SIFI viscoelastic solution, in order to allow the correct lens injection procedure.
   h. Carefully remove the loading chamber block by lifting it from below with thumb finger and holding the upper part with index and middle fingers (Fig.5). Check that the lens is located at the centre of the loading chamber (Fig. 6). Close the cartridge sides together until the "click-lock" mechanism engages (Fig. 7).
   i. Push forward the plunger softly and ensure that the silicone cushion correctly enters the loading chamber. Continue to push the plunger bringing the lens toward the tip of the injector.
      In the event the lens-injector system gets jammed, stop using the device.
3. Lens Injection
   a. Introduce the injector tip into the tunnel, with the sloping side facing down and inject the intraocular lens into the bag (Fig. 8).
   b. After the injection, pull out the injector from the incision.

Attention: When the loading chamber is introduced into the injector, the plunger should be in the pulled-back position. The injector tip must be handled with care, especially during insertion of the loading charge into the injector. It must not be damaged in order not to jeopardise the injection operation.

Device disposal
MINI WELL and MINI WELL PROXA are aspheric IOLs intended to be implanted in the posterior chamber of the eye, more precisely in the capsular bag. In case of disposal, the abovementioned medical devices must be considered as medical waste and disposed of as such (according to applicable national requirements).
The injector provided may be contaminated with potentially infectious substances of human origin after use. Dispose of the injector after use according to the applicable guidelines of biological hazardous waste.

Implant card
Fill in the implant card supplied with the medical device, reporting the required data and applying the adhesive label containing the identification data of the implanted lens. The compiled implant card must be given to the patient. Inform the patient to keep the implant card as a permanent record of the implant and to show it to any ophthalmologist to whom he/she will address in the future.
The meaning of the symbols on the implant card and label provided is described in the "Symbols" table contained within this package insert.

Limitations of Warranty and Liability
The intraocular lenses MINI WELL and MINI WELL PROXA must be implanted exclusively with the injector present in the package. SIFI S.p.A. assumes no responsibility for the use of said lenses models with injectors other than those that have been supplied.
The injector included in the package should not be dismantled nor manipulated. If the injector was manipulated, SIFI S.p.A. does not guarantee compatibility between lens and injector.
Furthermore, SIFI S.p.A. guarantees the compatibility of the system injector-intraocular lens only with the viscoelastic solution provided by SIFI S.p.A. In the absence of viscoelastic solutions provided by SIFI S.p.A. it is advisable to use ophthalmic viscosurgical devices (OVDs) with similar characteristics (check the information within the QR code printed on the products box).
SIFI S.p.A. assumes no responsibility for the use of different viscoelastic solutions or alternative techniques that could alter the normal functioning of the lens-injector system.

Expiry date
The expiry date refers to the sterility of the package. Do not implant the lens after the expiry date.

Notification of adverse reactions
Adverse reactions and/or potential complications should be reported to the local Vigilance Authorities and to:

SIFI S.p.A. – Via Ercole Patti, 36 – 95025 Aci Sant'Antonio (CT) Italy
e-mail: Vigilance@sifigroup.com

This information is required to document the potential long-term effects of the intraocular lens implant.

Summary of safety and clinical performance
The summary document of the information relating to the safety and clinical performance of the devices is available at the following URL:

https://ec.europa.eu/tools/eudamed

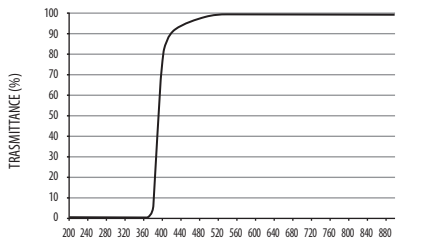
Calculation of dioptric power
Preoperative calculation of the power for these intraocular lenses should be determined by the surgeon's experience, preferences and intended lens placement.
Some power calculation methods for intraocular lenses are described in the following publications:

- Haigis W., "The Haigis formula". In: Shammas HJ., ed, Intraocular Len Power Calculations. Thorofare, NJ., Slack, 2004; 41-57.
- Hoffer KJ., "The Hoffer Q formula: a comparison of theoretic and regression formulas". J. Cataract Refract Surg. 1993 Nov;19(6):700-12.
- Basu S., "Comparison of IOL power calculations by the IOLMaster vs. theoretical calculations". Eye. 2006 Jan;20(1):90-7.
- Szaflik J., Kaminska A., Gajda S., Jedruch A., "Accuracy of the SRK II, SRK/T, Holladay and Hoffer Q IOL power calculation formulas in hyperopic patients after phacoemulsification". Klin Oczna. 2005;107(10-12):615-9. Polish.

Manufacturer
SIFI S.p.A. – Via Ercole Patti, 36
95025 – Aci Sant'Antonio (CT) Italy
www.sifigroup.com

PRODUCT INFORMATION

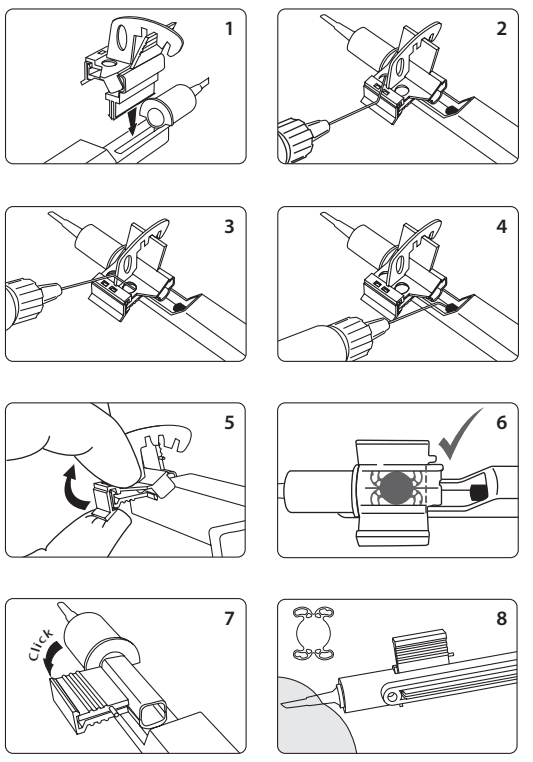
Curve of transmittance spectrum



- The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOLs made from acrylate copolymer with bonded UV-absorber.
- Transmittance spectrum was measured with a diameter of 6 mm using a disk of thickness equivalent to a 20D.
- UV cutoff ≤10% at 370nm

Fig. A

Instructions for use



4INSERTPIOLMDR00A 26/01/2024

SIFI S.p.A.
Via E. Patti, 36 - 95025 - Aci S. Antonio (CT) - Italy
www.sifigroup.com

Symbols

	Utilizzare prima di (anno – mese) Use before (year - month) Utiliser avant (annee – mois) Utilizar antes de (ano – mes) A se utiliza înainte de (anul – luna) Жарамдылық мерзімі (жыл - ай) Son kullanma tarihi (yıl-ay)	Utilizar antes de (ano – mês) Verwendbar bis (Jahr - Monat) Использовать не позднее (год-месяц) 在（年-月）前使用 پیش از این تاریخ مصرف شود (سال ماه) يستخدم قبل (سنة شهر)
	Consultare le Istruzioni per l'impiego Consult the instructions for use Lire le mode d'emploi Consultar las Instrucciones de uso Consultaţi instrucţiunile de utilizare Қолдану жөніндегі нұсқаулықты қараңыз Kullanım talimatlarına bakınız	Consultar as Instruções de uso Die Gebrauchsanweisung sorgfaltig durchlesen Смотри инструкцию по применению 请参考使用说明 به دستور العمل‌های مصرف مراجعه کنید برجاء مراجعة تعليمات الاستخدام
$Ø_P$	Diametro del Piatto Ottico (mm) Optical Plate Diameter (mm) Diametre du Corps Optique (mm) Diametro de optico (mm) Diametrul structurii optice (mm) Оптикалық беттің диаметрі (мм) Optik yüzey çapı (mm)	Diâmetro do prato ótico (mm) Plattendurchmesser (mm) Оптический диаметр (мм) 光学表面直径（毫米） قطر سطح چشمی نصف قطر القرص البصرى بالملليمتر
$Ø_T$	Diametro Totale (mm) Total diameter (mm) Diametre Total (mm) Diametro Total (mm) Diametrul total (mm) Жалпы диаметрі (мм) Toplam çap (mm)	Diâmetro total (mm) Gesamtdurchmesser (mm) Общий диаметр (мм) 整体直径（毫米） قطر كلى القطر الكلى بالملليمتر
	Fabbricante Manufacturer Producteur Fabricante Fabricantul Өндіруші Üretici	Fabricante Hersteller Изготовитель 生产商 شرکت سازنده المصنع
	Conservare all'asciutto Dry storage Conserver au sec Conservar en lugar seco Păstrare într-un loc uscat Құрғақ жерде сақтаңыз Kuru olarak saklayın	Conservar a seco Trocken lagern Хранить в сухом месте 干燥保存 در جای خشک نگهداری شود يحفظ في مكان جاف
	Non riutilizzare Do not reuse Ne pas reutiliser No volver a utilizar A nu se reutiliza Қайта қолдануға болмайды Tekrar kullanmayın	Não reutilizar Nicht wieder verwenden Не подлежит повторному использованию 不要重复使用 دوباره استفاده نشود لا يستخدم
STERILE	Sterilized using steam Sterilizzato a vapore Stérilisé à la vapeur Esterilizado a vapor Sterilizat cu aburi Бумен зарарсыздандыру Buhar kullanılarak sterilize edilmiştir	Esterilizado a vapor Mit Dampf sterilisiert Стерилизовано посредством пара 消毒用蒸汽 استریل‌شده با بخار معقم باستخدام البخار
	Limitazione nella temperatura di conservazione/trasporto Limitations in storage/transport temperature Limitation dans la température de conservation / de transport Limitación en la temperatura de conservación/transporte Limitări ale temperaturii în timpul depozitării/transportului Сақтау/тасымалдау температурасына қойылатын шектеулер Saklama/taşıma sıcaklığındaki kısıtlamalar	Limite da temperatura de conservação/transporte Beschränkung der Lager-/Transporttemperatur Ограничения по температуре хранения/перевозки 存储/运输温度限制 حدود درجة الحرارة للتخزين/النقل محدودیت های نگهداری/دمای حمل و نقل
CE 0426	Marchio CE e codice dell'Ente Notificato CE Mark and Notified Body Code Marquage CEet code de l'Organisme Notifie Marcado CE y codigo del Organismo Notificado Marcajul CE şi codul organismului notificat CE белгісі және өкілетті орган берген код CE işareti ve Onaylı Kuruluş kodu	Marca CE e código da Entidade Notificada CE-Kennzeichnung und Code der Notifizierten Stelle Маркировка CE и код, присвоенный уполномоченным органом CE 标志和认证机构代码 CE نشان NB و کد علامة الاتحاد الاوربى واخطار الهيئة
	Nome Paziente o ID Paziente Patient Name or patient ID Nom du patient Nombre del paciente Numele pacientului sau datele de identificare ale pacientului Аты-жөні немесе пациенттің жеке куәлігі нөмірі HastaAdıveyaHastaKimliği	Nome do paciente ou identificação do paciente Name oder ID des Patienten Имя и фамилия или ИН пациента 患者名字或者患者ID نام بیمار یا شناسه بیمار اسم المريض أو الرقم التعريفي الخاص به
	Data dell'impianto Date of Implantation Date de l'implant chirurgical Data del implante Data implantării Имплантация жасалған күн ImplantasyonTarihi	Data do implante Implantationsdatum Дата имплантации 植入日期 تاریخ پیوند تاريخ التركيب
	Nome e indirizzo della struttura sanitaria dell'impianto / operatore Name and Address of the implanting healthcare institution / provider Nom et adresse de la structure sanitaire de l'implant chirurgical / professionnel de santé Nombre y dirección del centro sanitario del implante / profesional sanitario Denumirea şi adresa instituţiei medicale care efectuează implantarea/funrizorului Имплантация жасайтын медициналық мекеменің / денсаулық сақтау ұйымының атауы және мекен-жайы İmplanteedensağlıkkurumunun/sağlayıcısınınadıveadresi	Nome e endereço do estabelecimento de saúde que implantou/fornecedor Name und Anschrift der einsetzenden Gesundheitsbehörde / des Providers Название и адрес медицинского учреждения / здравоохранительной организации, осуществившей имплантацию 植入医疗机构/提供商的名字和地址 نام و نشانی موسسه/ارائه‌دهنده خدمات درمانی پیوند سم وعنوان المؤسسة الصحية / مقدم الخدمة
	Sito web informativo per i pazienti Information website for patients site web d'information pour les patients sitio web informative para los pacientes Website de informare a pacienţilor Пациент туралы ақпарат веб-сайт Hastalariçinbilgisitesi	Sítio Internet com informações para os pacientes Webseite mit Informationen für Patienten Информационный вебсайт для пациентов 给患者的信息网站 وبسایت اطلاعرسانی ویژه بیماران موقع معلومات للمرضى
MD	Medical device / device Name Dispositivo Medico / Nome dispositivo Dispositif médical / Nom du dispositif Producto sanitario / Nombre del producto Dispozitiv medical / Numele dispozitivului Медициналық құрылғы / құрылғының атауы Tıbbi cihaz/cihaz adı	Dispositivo médico / Nome do dispositivo Medizinprodukt / Produktname Медицинское устройство / имя устройства 医疗设备/设备名称 دستگاه پزشکی / نام دستگاه جهاز طبي/ اسم الجهاز
SN	Numero di serie Serial Number Numéro de série Número de serie Număr de serie Сериялық нөмір Seri numarası	Número de série Seriennummer Серийный номер 序列号 شماره سریال الرقم التسلسلي
LOT	Numero di lotto Lot Number/Batch code Numéro de lot Número de lote Număr lot/Cod identificare lot Партия нөмірі / Өндірушінің бума коды Lot kod numarası	Número do lote/Código da remessa Losnummer Номер поставляемой партии / Код партии производителя 批号/批代码 شماره گروه/کد دسته رقم المجموعة / رمز الدفعة
UDI	Sistema UDI (sistema di identificazione unica del dispositivo) UDI System (Unique Device Identification system) Système UDI (système d'identification unique du dispositif médical) Sistema UDI (identificación única del dispositivo) Sistem UDI (Sistem Identificare Unică a Dispozitivului) ҚЕҚ жүйесі (Құрылғыны Ерекше Сәйкестендіру) UDI Sistemi (BenzersizCihazTanımla masistemi)	SistemaUDI (Sistema de identificação única do dispositivo) UDI-System zur Systemidentifikation Система ИУС (Идентификации уникального устройства) UDI系统（设备统一识别系统） سامانه UDI (سامانه شناسه اختصاصی دستگاه) النظامالفريدلتعريف الجهاز
	Attenzione Caution Attention Atención Atenţie Назар аударыңыз Dikkat	Atenção Achtung Обратить внимание 注意 توجه انتبه
	Singolo sistema di barriera sterile Single sterile barrier system Système de barrière stérile simple Sistema de barrera estéril simple Sistem cu barieră sterilă unică Бір стерильді тосқауыл жүйесі Tekli steril bariyer sistemi	Sistema de barreira estéril única einfach steriles Barriesystem Одинарная стерильная барьерная система 单层无菌屏障系统 نظام حاجز مُعقم فردي سیستم مانع استریل منفرد
	Doppio sistema di barriera sterile Double sterile barrier system Système de barrière stérile double Sistema de barrera estéril doble Sistem cu barieră sterilă dublă Қос стерильді тосқауыл жүйесі İkili steril bariyer sistemi	Sistema de barreira estéril dupla doppelt steriles Barrieresystem Двойная стерильная барьерная система 双层无菌屏障系统 نظام حاجز مُعقم مزدوج سیستم مانع استریل دوتایی
REF	Numero catalogo Catalogue number Numéro de catalogue Número de catálogo Număr catalog Каталог нөмірі Katalog numarası	Número do catálogo Artikelnummer Каталожный номер 目录号 رقم الكتالوج شماره کاتالوگ
#	Numero modello Model number Numéro de modèle Número de modelo Număr model Үлгі нөмірі Model numarası	Número do modelo Modell-Nr. Номер модели 型号 رقم الموديل شماره مدل
	Data di produzione Date of Manufacture Date de fabrication Fecha de fabricación Dta fabricaţiei Өндірілген күні Üretim Tarihi	Data de fabrico Herstellungsdatum Дата изготовления 生产日期 تاريخ التصنيع تاریخ ساخت