Dear valued customer

This catalogue introduces a new brand: ‘ophthafutur®.

‘ophthafutur® is more than just a standard product line. The brand faces all current and future challenges in the ophthalmic sector. It offers unique and smart solutions, supported and counselled by a multidisciplinary group of experts. These experts come from the fields of ophthalmology, chemistry, pharmacy, biology and physics.

The primary goal of the brand is the generation of new product ideas, development, registration and marketing of related products.

The introduction of the new European guidelines and other requirements from around the world results in a rise of expectations from all stakeholders: international health authorities, notified bodies, as well as surgeons and patients asking for products manufactured to the highest pharmaceutical and regulatory standards, offering outstanding quality. The ‘ophthafutur® product line responds to this market demand.

The co-operation of clinicians and scientists with an experienced manufacturer enables a rational problem solving approach, aided by a very successful history of 25 years in pharmaceutical production, quality control, device manufacturing and drug synthesis. We aim to offer superior quality products conforming to the most demanding requirements. Further benefits are ease of use, modern packaging and clear labeling.

One source for innovation will be the adoption of new surgical techniques, high-tech engineering, novel materials and developments around well-established products. A better understanding of the interaction of medical devices with tissues during surgery, as well as their newly defined bio-chemical and physical impact will offer new opportunities.

‘ophthafutur® represents an innovative and creative environment in which you can become an important part. We invite you to join with us in your role as surgeon or scientist.

Please contact the ‘ophthafutur® team with your ideas and needs. We can then discuss and evaluate your thoughts for successful inclusion into the ‘ophthafutur® concept.

‘ophthafutur®
nomen est omen –
the name says it all

Your ‘ophthafutur® team

Information as of: 01/2019

O1000-3-2
**novel approaches to illuminate the eye**

Currently, light fibres connected to external light sources are used to illuminate the posterior chamber of the eye.

Controlling the light intensity reaching the retina, the distance to the retina, as well as the exposure time of light is currently not possible using these fibres.

Novel approaches using specially designed light sources within the eye are very promising. In addition the interaction of illumination with tissues and ophthalmic liquids is currently being studied.

**novel approaches to tissue removal**

As various media are used during surgery, the interaction of energy (induced by Laser or ultra-sound) with these media and the intra-ocular tissue must be well understood.

A consortium of six partners with a broad experience in the fields of ophthalmic surgery, optics, engineering, industrial manufacturing and design of medical devices investigates the possibility of removing delicate tissues in and around the eye.

The technology is based on a novel 2.94 μm approach for very efficient use of laser light as a surgical tool.

**novel approaches to package design & labeling**

Packaging and labeling require constant attention. Up to date packaging must be accurate, environmentally friendly, user friendly and attractive.

It is very challenging to combine all these features with non-verbal communication, safe labeling, coding (UDI: unique device identification) and forgery protective elements.

ophthafutur® shows new ways and develops creative, safe and convenient packaging.
Inferior retinal detachments are currently treated by heavy mixtures of silicone oils and semifluorinated additives. Due to the toxic profile of the additives, which are masked by the silicone oil, new substances are needed.

Inhomogenities are reported.

At low temperatures the components of the mixtures can potentially separate from each other.

A one part heavy liquid is needed.

Avoiding additives in silicone oil is the first step to developing an alternative product. Chemically binding fluor atoms to the silicone oil backbone network also avoids the usage of mixtures.

All volatile components are removed by the application of a proprietary purification processes.
ophtha futur® sil heavy

ophtha futur® sil heavy is a one part liquid with a density of 1.07 g/cm³. The product has been purified applying Pharmpur silicone oil purification technology.

Heavy oil can be used in the treatment of inferior retinal detachment without the worry of low temperature storage or interaction of additives with the intraocular tissue.

Avoids head down position
Additive free
Safe and easy application
Heavier than water
Chemically stable
Highly purified
<table>
<thead>
<tr>
<th>Product</th>
<th>Article-Nr.</th>
<th>Spec.-Nr.</th>
<th>Units per box</th>
<th>Filling quantity [ml]</th>
<th>Dimension [mm x mm x mm]</th>
<th>Weight [g]</th>
<th>Shelf Life [months]</th>
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<tr>
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<td><strong>coming soon ...</strong></td>
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THE ISSUE

manufacturing-related impurities
Perfluorooctane and Perfluorodeca-line are both liquids consisting from carbon and fluorine atoms only. For use as a medical device, it is essential that no other atoms (like Hydrogen: H) are bound in the molecules. Such alterations in the atomic structure can result in very reactive molecules, subsequently leading to tissue interaction. Incompletely fluorinated molecules can potentially damage the sensitive tissues within the eye.

A measure for the purity of a Perfluorocarbon is the H-Value. The H-value summarizes all impurities which relate to the presence of Hydrogen (H) containing compounds. A whole library of such compounds can be present even in incomplete purified products and each of these compounds can create a severe adverse reaction. Standard procedures of purifying and analytical controls are not sufficient to separate or detect the toxic impurities.
Our answer: ultra-purified perfluorocarbon liquids

ophtha futur® octa and deca are highly purified by a unique and multi-step process. During the ultra-purification, all potential impurities are removed down to a level of not more than 10 ppm, which represents the limit of quantification. The in-process controls are very strict during manufacturing and analytics of ophtha futur® products. This results in a product which is finally purified to the highest extent.

The purification steps are monitored and the success of the purification process is verified. Final products are only accepted if the H-value is below 10 ppm.
intended use

Perfluorocarbon liquids (PFCL) are used for intraoperative unfolding and repositioning/fixation of a detached retina. Furthermore, these liquids simplify the removal of luxated lenses and foreign bodies from the vitreous.

handling

PFCL, due to their high density, sink to the bottom of the eye. When applied, the liquid should be slowly injected over the papilla until a small bubble forms. The tip of the injection cannula should then be kept within the bubble, gently enlarging it.

When removing PFCL, the user should ensure complete removal.

Remnants of PFCL may cause adverse reactions such as inflammation and could lead to interactions with subsequently filled silicone oil.

It is not recommended to directly exchange the PFCL with silicone oil to avoid direct contact between the two substances.

novel high performance polymer syringes (HPPS)

As glass syringes add considerable weight (uncomfortable for the surgeon) and PFCL can possibly interact with the lubrication of glass syringes, we introduced a novel filling technology.

Using HPPS syringes avoids contact between the perfluorocarbon liquid and the standard lubrication used in glass syringes. This measure increases safety and reduces the likelihood of sticky effects or emulsification.

Preloaded syringes offer an ideal solution for the surgeon: They are easy to prepare and use. An ergonomically designed fingerplate was created to aid control and comfort.
### Parameters

<table>
<thead>
<tr>
<th></th>
<th>Tamponade</th>
<th>Perfluoro-n-octane C₈F₁₈</th>
<th>Perfluorodecalin C₁₀F₁₈</th>
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<td>100%</td>
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<tr>
<td>Perfluoro-N-Octane</td>
<td>–</td>
<td>–</td>
<td>≥ 95%</td>
</tr>
<tr>
<td>Perfluorodecalin</td>
<td>–</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Refractive Index n₀²⁰</td>
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<td>1.31</td>
<td></td>
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<tr>
<td>Density (20 °C)</td>
<td>1.77 g/ml</td>
<td>1.93 g/ml</td>
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<td>H_value (Concentration of C-H Compounds)</td>
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<td>&lt; 10 ppm</td>
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<td>Boiling Point</td>
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<td>≤ 0.5 EU/ml</td>
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Product Sterility
- Sterile Filtration

Outer Surface Sterility
- Steam Sterilisation

**Cell Toxicity (%)**

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<th>8</th>
<th>14</th>
<th>36</th>
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<td>700</td>
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### Compound

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<th>Surface Tension mN/m</th>
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<tr>
<td>1H-Perfluoro-n-octane</td>
<td>15</td>
</tr>
<tr>
<td>Perfluorodecalin</td>
<td>19</td>
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</tbody>
</table>

**Interfacial Tension Against Water mN/m**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Perfluoro-n-octane</td>
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<tr>
<td>1H-Perfluoro-n-octane</td>
<td>32</td>
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<tr>
<td>Perfluorodecalin</td>
<td>53</td>
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### Presentation

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<th>Filling Volume</th>
<th>Container</th>
<th>Sterile Barrier</th>
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<tbody>
<tr>
<td>‘ophthafutur® deca</td>
<td>5 ml / 7 ml</td>
<td>vial</td>
<td>pouch</td>
</tr>
<tr>
<td>‘ophthafutur® deca</td>
<td>5 ml / 7 ml</td>
<td>syringe</td>
<td>pouch</td>
</tr>
<tr>
<td>‘ophthafutur® octa</td>
<td>5 ml / 7 ml</td>
<td>vial</td>
<td>pouch</td>
</tr>
<tr>
<td>‘ophthafutur® octa</td>
<td>5 ml / 7 ml</td>
<td>syringe</td>
<td>pouch</td>
</tr>
</tbody>
</table>
ophtha futur®

octa & deca
products

High patient and product safety

Multi-step proven & tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

3 years shelf life

Novel high performance polymer syringes (HPPS)
THE ISSUE

CO2 emissions

environment
Due to their impact on our environment, fluorinated gases have been banned from a wide range of industrial applications. However, some gases are still available for medical purposes.

Premixed gases, as well storage containers currently used (bottles, cans) can raise legal and/or stability concerns.

As the demand for gas is constantly increasing, the challenge is to support and preserve our environment. The aim must be to release as little gas as possible during the surgical procedure.
In borosilicate glass containers, the gas is stored in a non-pressurized state. The glass container is gas tight and does not allow any exchange with the external environment. The gentle sterilization process allows safe storage of the gas.

The system helps to protect the environment by offering only the quantities which are needed in the OR, thus minimizing waste.

The surgeons can adjust the gas concentration mixture to their needs without releasing too much gas into the environment.
SF₆, C₂F₆ and C₃F₈ are chemically and physiologically inert, colourless, and odourless gases for tamponading retinal detachments after vitrectomy.

**application system**

ophthafutur® gas is supplied in glass containers. The system also includes a preassembled sterile plastic syringe to prepare the gas mixture and a small gauge needle to facilitate the injection. A patient information card and a patient bracelet are also included.

**preparation of gas mixtures**

The illustration shows the single steps of the preparation of gas / air mixtures including handling instructions. The gas is offered in a non-pressurized glass container. The pure gas is drawn into the larger sterile plastic syringe (see step 1–4 of the illustration). After the transfer, the surgeon can mix the gas with filtered ambient air.

Prior to mixing the excess of the pure gas which is not needed to prepare the mixture is expelled from the syringe. Ambient air is then drawn in through the filter into the plastic syringe. The amount of air determines the resulting mix ratio (step 5–8 of the illustration).

**application**

Ensure the vitreous body has been completely removed before applying SF₆, C₂F₆ or C₃F₈.

It should be considered that pure gases will expand, when purely injected into the eye. There is an equilibrium between gas and ambient air at which the gas mixture will not expand. Values from the literature are given to indicate possible non-expansive mixtures. Please be aware to carefully check the mixing process.

A small gauge needle is included to aid the injection of gas. This allows the surgeon to finally adjust the gas pressure within the eye after removing all surgical accessories. Patients who have received gas should be provided with the patient information card and a bracelet should be attached to their wrist. Patients should be made aware of the possible hazards when a gas bubble is present in the eye.

**warnings**

Patients with a gas tamponade must not be exposed to pressure variations (flying, diving, etc.). Nitrous oxide anaesthesia must be interrupted at least 20 minutes before applying SF₆, C₂F₆ or C₃F₈.
Composition

$\text{SF}_6$ consists of sulfur hexafluoride with an initial purity of $> 4.5$ (Mass fraction $> 99.995\%$) and density of $6.07 \text{ kg/m}^3$ (1 bar, 20 °C).

$\text{C}_2\text{F}_6$ consists of hexafluoroethane with an initial purity of $> 5.0$ (Mass fraction $> 99.999\%$) and density of $5.84 \text{ kg/m}^3$ (1 bar, 15 °C).

$\text{C}_3\text{F}_8$ consists of octafluoropropane with an initial purity of $> 4.0$ (Mass fraction $> 99.99\%$) and density of $8.17 \text{ kg/m}^3$ (1 bar, 15 °C).

Properties

Filling quantity glass reservoir
$\text{SF}_6: 15 \text{ ml} \quad \text{C}_2\text{F}_6: 12 \text{ ml} \quad \text{C}_3\text{F}_8: 9 \text{ ml}$

Total syringe volume
$60 \text{ ml}$

Possible effective tamponade duration of the gases [days]:

$\text{SF}_6$: 6
$\text{C}_2\text{F}_6$: 15
$\text{C}_3\text{F}_8$: 30

Possible retention time of the gases [days]:

$\text{SF}_6$: up to 14
$\text{C}_2\text{F}_6$: up to 35
$\text{C}_3\text{F}_8$: up to 65

Packaging aid: quick guide, patient safety card and patient bracelet (including individuell insert), injection needle, instruction of use and product stickers.
ophtha futur®
gas
products

High purity
Improved convenience
Adjustable gas concentration
Environmental friendly
Enhanced safety
THE ISSUE

manufacturing-related impurities

risks of silicone oil endotamponades

With silicone oils, as with all polymers, the characteristics are determined by chain length and chain length distribution. Risks originate from volatile and short-chained components which are generated during production. These components can penetrate into tissue and damage cells.

Due to the combination of hydrophobicity and polarity, silicone oils can act as a trap for many impurities that can destabilize the tamponade ("emulsification"), even in low concentrations.
Our response: ultra-purified silicon liquids

ophthafutur® silicone oils are ultra-purified according to a multi-step FDA approved process, which is successfully performed since 1998. By combining extraction, thermal treatment and filtration, all critical impurities are separated. The materials of the primary containers are selected to prevent any recontamination during manufacturing and storage.

Purity criteria for silicone oils

In addition to the well-established GC-MS methods, the control of the removal of short-chained compounds by gel permeation chromatography (SEC) is an ophthafutur® standard.
intended use

Silicone oils are used as ocular endo-
tamponades in cases of severe re-
tinal detachment, e.g. solid prolifera-
tive vitreo-retinopathy, traumatic
detachment and giant tears, as well
as other detachments of the retina,
which cannot be treated with other
forms of therapy.

Silicone oil can be injected into the
eye with the support of vitrectomy
machines. An adapter kit of the
‘ophthafutur®’ line will support the
oil injection.

Silicone oils exhibit a density
< 1 g/cm³. For this reason the oil
will float on water.

The eye should be completely filled
with silicone oil to avoid cavities
which may still contain water or gas.

To avoid high intraocular pressure,
the patient should be monitored
postoperatively. Due to the lower
density, an iridectomy at 6 o’clock
should be considered.

Emulsifications are one of the known
side effects of oil injections and can
be triggered by various reasons.
In addition to the precondition of the
patient, the quality of the injected oil
may play a role. The likelihood of
emulsifications can be reduced by
using ultrapurified oil.

The standard glass syringe, which
is widely used in ophthalmology has
a plastic luer lock at the tip. For
added protection of the luerlock and
safer handling, a mechanical support
tube is shrunk over the tip.
**Parameters**

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<tr>
<th>Tamponade</th>
<th>Poly (Dimethylsiloxane)</th>
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<td>Molar Mass (kDa)</td>
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</table>

| Density (25 °C) | 0.97 g/cm³ |
| Interfacial Tension vs. Water (35 °C) | 39 mN/m |

**Silanol Content**

| Content Volatile Oligosiloxanes (HS-GC/MS) | < 100 ppm |
| DMCPS/D5 | ≤ 10 ppm |
| DMTS/MD2M | ≤ 10 ppm |
| HMDS/MM | ≤ 10 ppm |
| HMCTS/D3 | ≤ 10 ppm |
| OMCMS/D4 | ≤ 10 ppm |
| OMST/MDM | ≤ 25 ppm |
| ∑ | ≤ 25 ppm |

**Acetone Content (HS-GC/MS)**

| < 10 ppm |

**Mass Loss**

| ≤ 0.1% |

**Polydispersity**

| 1.0 – 2.3 |

**Refractive Index nD**

| 1.404 |

**Filling Volume**

| 10 ml Syringe |

**Sterilisation**

| Steam Sterilisation |

**Bacterial Endotoxins**

<p>| ≤ 0.5 EU/ml |</p>
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<th>5000 mPas</th>
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<td>Interfacial Tension vs. Water (35 °C)</td>
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<td>∑ ≤ 25 ppm</td>
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<td>Bacterial Endotoxins ≤ 0.5 EU/ml</td>
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High patient and product safety
Multi-step proven and tested ultra-purification process
Safe, biocompatible, sterile, endotoxin-free products
3 years shelf life

Pharmpur GmbH
Messerschmittring 33
D-86343 Königsbrunn
Deutschland
safety
The world-wide ambition to reduce the acceptable concentration of bacterial endotoxins is a major challenge in manufacturing, especially for products derived from natural raw materials.

HPMC (Hydroxypropylmethylcellulose) is made from natural cellulose. Microbial impurities are therefore a major concern.

The main goal during ophthalmic surgery is to obtain an unobstructed view through the clear media of the eye. Bubbles contained in any liquid product may considerably obstruct the surgeon’s view. The supply of HPMC having a sufficiently high viscosity paired with an easy and simple injectability represents an additional challenge.
Our response: scientifically-based engineering

‘ophthafutur®’ hpmc is a dispersive ophthalmic viscosurgical device (OVD). Characterized by good wetting properties, excellent tissue and endothelium protection, efficient volume replacement and quick removal.

‘ophthafutur®’ viscoelastics are in compliance to the standards of pharmaceutical products and are manufactured according to the relevant GMP guidelines in a fully controlled clean room environment. The filling is performed under pharmaceutical class A conditions avoiding any product contamination. Vacuum technology enables bubble free filling.

GMP environment
advanced filling technology
fields of application are:

ophthafutur® hpmc can be used for various purposes. The product can be used either intraocularly or extraocularly. It allows excellent visualization when used during surgery due to the absence of bubbles.

ophthafutur® hpmc can be used to wet the cornea during cataract, corneal or retinal procedures. The syringe allows an easy application of the product under a microscope.

The product may also be used to lubricate the surfaces of IOL injectors or IOL cartridges.

The patient should be monitored accordingly after surgery, as elevated intraocular pressure may occur.
**Parameters**

- **OVD**
- **Hydroxypropylmethylcellulose (HPMC)**
- **Molar Mass** 80 kDa
- **Filling Volume** ≥ 2.0 ml
- **HPMC Content** 2 % (m/m)
- **pH** 7.0
- **Bacterial Endotoxins** ≤ 0.2 EU/mL
- **Osmolality** 285 mOsm/kg
- **Viscosity (20 °C)** 3,500 – 6,000 mPas
- **Sterility** Steam Sterilisation
- **Refractive Index n_\text{D}^{35}** 1.336

Injection of hpmc was investigated by using a variety of injection needles. To ensure safe injection, the surgeon should select the appropriate needle due to the variances of inner diameters between manufacturers of 23g outer needles.

**23 G Cannulas – The Inner Diameter Makes The Difference**

<table>
<thead>
<tr>
<th>Type</th>
<th>Viscoflow</th>
<th>4001B</th>
<th>1274A</th>
<th>M3909</th>
<th>4001CTW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inner Diameter (mm)</td>
<td>0.30</td>
<td>0.32</td>
<td>0.33</td>
<td>0.42</td>
<td>0.42</td>
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</tbody>
</table>
Crystal clear view
Endotoxin free
Preloaded syringe
quality standards

The whole product life cycle of the opthafutur® product lines is controlled by an integrated management system incorporating the activities of all partners involved.

The products are manufactured strictly according to the relevant GMP standards, especially EU GMP Guideline, ISO 13485, 21CFR 820 and 211, CAN/CSA-ISO 13485, ANVISA RDC 59/2000, KGMP (Korea), I.R. Iran GMP


Manufacturing authorization for Medicinal Products (Regierung von Oberbayern DE_BY_04_MIA_2011_0023).

FDA listed contract manufacturer (www.fda.gov, FDA FEI number 3005689226).

A modular system of manufacturing as well as documentation processes enables optimized and highly efficient validation and qualification procedures of all relevant processes and equipment. On this basis, medical devices and pharmaceuticals can be manufactured on an equivalent quality level. This was and is frequently confirmed by inspections of the world leading health agencies over the last two decades.

The whole opthafutur® team intends to maintain and further improve the high level of the integrated quality system and to support our customers with related results and experiences.
Pharmpur GmbH is the exclusive manufacturer of the "ophthafutur®" products. Pharmpur can look back to a 25 years successful history with the focus on contract manufacturing. Millions of units of ophthalmic liquids manufactured at Pharmpur have been used all over the world.

Pharmpur is one of the European pioneers of purifying perfluorocarbon liquids and silicone oils for ophthalmic use. The chemist Dr. D.-H. Menz played the leading role as managing partner as well as inventor and developer of products and processes of Pharmpur, reflected in numerous papers and patents.

Over the years the company was organically developed into a state of the art organisation with expertise in analytics, manufacturing of medical devices and pharmaceuticals, product development and quality management.

A young and highly educated staff ensures the continuous further development of the company.

**Pharmpur GmbH is the exclusive manufacturer of the "ophthafutur®" products.**

**Manufacturing excellence – made in Germany**

The concept of combining all critical production steps under one roof guarantees conformity and excellent quality. The quality of the raw materials, which are synthesized and ultra-purified according to proprietary processes, meets the highest standards in international comparison.

Pharmpur maintains validated procedures for compounding, aseptic filling, autoclaving and dry heat sterilization. These procedures are completed by all associated packaging processes. A dense network of quality controls is performed per batch in own, fully equipped laboratories.

**Product-portfolio**

Pharmpur is specialized in the fill-finish manufacturing of ready-to-use syringes and vials.

The product range covers gases, products of low and high viscosity and gel-type media (viscoelastic substances). The manufacturing processes, as well as the documentation processes, are based on a modular system which allows an efficient process management employing optimized validation strategies.
purity  safety  environment