

Quality time for better care



PHARMACEUTICAL

We're bringing clarity to Ophthalmics



Terumo Injection Filter Needle

Indicated for hypodermic and intravitreal injection

A first step of the INFINO™ -Development Program

Terumo Injection Filter Needle at a glance

A new needle within Terumo's portfolio – indicated for hypodermic and intravitreal injections.

The Injection Filter Needle is the first example of a marketed product as part of the INFINO™ -Development program

Focusing on intravitreal injection

Globally, around 8 million people suffer from age-related macular degeneration; the equivalent figure for diabetic retinopathy is 3.9 million¹. Intravitreal injections can deliver effective treatments for both, and in developed countries their use is rising fast. Analysis at a leading UK eye hospital, for instance, revealed an 11-fold increase in intravitreal injections from 2009 to 2019; projections to 2029 indicate an additional increase of 85%².

Optimized solutions for intravitreal injection are becoming increasingly important.

Verified and validated for intravitreal applications

Recent field safety notices point to the practice of using injection needles off-label for intravitreal application.

For **Terumo Injection Filter Needle** all the verification and validation activities required for a specific indication for intravitreal injection are in place to offer a complete solution when combined with a similarly validated syringe.

Terumo Injection Filter Needle is compatible with all syringes compliant to EN ISO 80369-7.

For those working to improve safety, precision and customer experience, for injection into sensitive areas such as the vitreous.

- **Integrated 5µm mesh filter**
- **30G-12mm extra-thin wall cannula**
- **Soft blister packaging for aseptic presentation.**

The Terumo Injection Filter Needle has a (an):

- 30G Extra-thin-wall cannula
- Terumo K-Pack II needles with 30G ETW cannula show more than 4 time higher flow rates compared to regular wall
- Hub: Polymethylmethacrylate and color masterbatch in accordance with European Pharm 3.1.3. "Polyolefins".
- Cannula: Stainless steel type X5CrNi18-10 in accordance with ISO 15510 and EN 10088-1
- Adhesive: Acrylic glue (UV cured)
- Lubricant: Silicone oil complying with European Pharm. 3.1.8. Silicone oil used as lubricant
- Filter: Polyamide, 5µm mesh opening
- Protector: Polypropylene

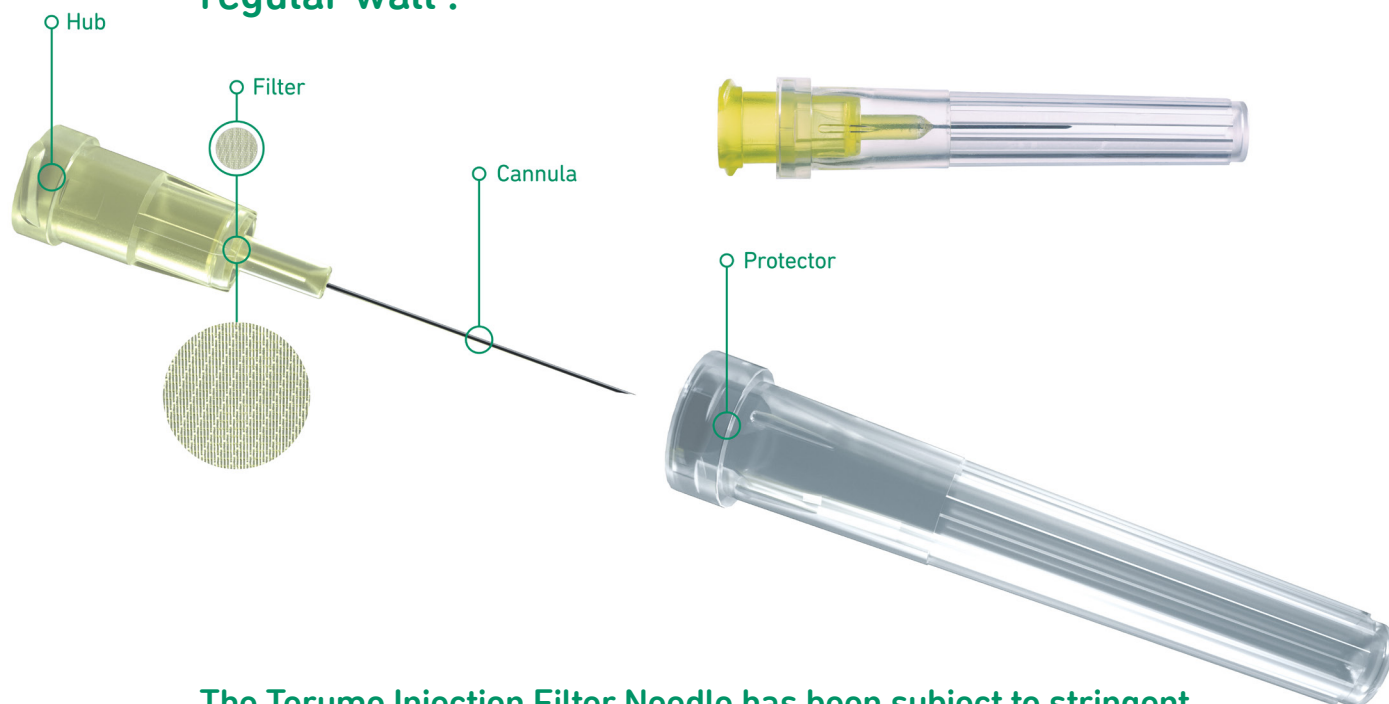
It is supplied in individual foil-paper blisters, 100pcs per unit box, 3000 pcs per shipping carton.

Take a closer look

| Needle Gauge | Needle Outer Diameter | Needle Length | Wall Thickness | Bevel Angle | Filter Pore Size |
|--------------|-----------------------|---------------|-----------------------|-------------|------------------|
| 30G | 0.3mm | 12mm / 1/2" | Extra Thin Wall (ETW) | 12° | 5µm |

Products do not contain components made of natural rubber latex CE0197 

Terumo K-Pack needles 30G with ETW-cannula show more than 4 times higher flow rate compared to regular wall*.



The Terumo Injection Filter Needle has been subject to stringent and extensive testing to determine biological properties and filtration performance and to meet sterility requirements:

| | |
|-------------------------------------|---|
| Biological properties: | Biological evaluation has been performed in accordance with EN ISO 10993-1. |
| Particle levels²: | When tested with the light obscuration particle count method according to EP 2.9.19, USP 788 (method 1) and USP 789, the average number of sub-visible particles found in the needles does not exceed: <ul style="list-style-type: none"> – Particles $\geq 10 \mu\text{m}$: Not more than 10 particles per device – Particles $\geq 25 \mu\text{m}$: Not more than 1 particle per device – Particles $\geq 50 \mu\text{m}$: Not more than 0 particles per device |
| Sterility: | <ul style="list-style-type: none"> – Products are supplied STERILE. – The sterile barrier system meets the requirements of EN ISO 11607-1; – The packaging process is validated in accordance with EN ISO 11607-2. – Needles are sterilized with Ethylene Oxide gas, in package, using a validated sterilization process (EN ISO 11135) to assure a Sterility Assurance Level of at least 10 (EN 556-1). |

Contact a Terumo Pharmaceutical Solutions Expert today to find out more about INFINO™ Program and how it could help you

Disclaimers:

- The **Terumo Injection Filter Needle** is a sterile medical device for single use intended to inject fluids. The indications for use are for general application – for treatment – injection of fluids into parts of the body below the surface of the skin and into the vitreous
- In case of injection of fluids into⁶ the vitreous, the **Terumo Injection Filter Needle** shall be used only in combination with (pre-)filled syringes validated for intravitreal use.
- This information is intended for professionals in the pharmaceutical supply chain who are interested in primary packaging, injection components and medical devices from Terumo Pharmaceutical Solutions, for use in combination with their respective drug products (hereafter, pharmaceutical professionals). Please note that the product information contained on this data sheet is exclusively addressed to pharmaceutical professionals. This product information is not for the general public, nor is it intended to be a substitute for professional medical advice or for the care that patients receive from their healthcare professionals
- Please note that some products may not be available in all regions, please reach out to your local Terumo Medical Care Solutions – Pharmaceutical contact for details.
- All brand names are trademarks or registered trademarks owned by TERUMO CORPORATION, its affiliates, or unrelated third parties.
- Images are for visualization purpose only.
- Always consult the product label and instructions for use for a complete overview of complications, warnings, cautions and precautions prior to actual use.
- **INFINO™** is a trademark filed by Terumo Europe N.V. for medical devices to be developed with specific features, the first example of these products is currently marketed as “Terumo Injection Filter Needle”

*Data on file

1 World Health Organization ‘Blindness and Vision Impairment’ 10th August 2023,
Available to view at: <https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment>

2 R. Chopra et al ‘Intravitreal injections: past trends and future projections within a UK tertiary hospital’ Eye (36) 1373-1378 (2022)