

## 1. Product Information

|                 |  |
|-----------------|--|
| Product(group): | Monofilaments  |
| Basic UDI-DI:   | 89660000532Monofilament7A  |
| Intended User:  | To be used by qualified users in the medical field, e.g. doctors, specialists, nurses, physiotherapists and pedicures. |
| Intended Use:   | A monofilament is a device intended for assessing the loss of protective sensation.                                    |













## 2. General Instructions

It is very important that all terms and conditions in this Instructions for Use are met, and that all information is carefully read and followed. If this is not the case, these monofilaments should not be used.

If you have any questions regarding these instructions, you can contact us regarding the (re-) use of these monofilaments. Our contact details can be found under § 9 of this instruction.

 **Read all instructions carefully before use**

## 3. Symbols Used

|   |   |   |   |
|---|---|---|---|
|    | Article number / Article reference manufacturer           |    | Indication that the product is a 'Medical Device'                             |
|    | LOT-number  |    | Indication that the product is delivered 'Non Sterile'                        |
|    | Electronic Instructions for Use (accessible via e-ifu.nl) |    | Product complies with the applicable laws and regulations for medical devices |
|  | UDI - Unique Device Identifier                            |  | Keep packaging dry  |
|  | Date of Manufacture                                       |  | Manufacturer (details)  |
|  | Importer (details)  |  | European Representative (details)   |

## 4. Processing Instructions

### Before (first) use

Before first use the monofilament must be cleaned and disinfected. In case of re-use the device should be cleaned and disinfected in between usages.

### Verification and Safety check

Each monofilament must undergo a visual inspection before each use. Not only pay attention to whether the device has been properly cleaned and disinfected, but also to whether the monofilament still functions in the correct manner. Therefore, before each use, check that all parts are attached and that the device does not show any defects or signs of material degradation.

### Cleaning and Disinfecting

Cleaning and disinfecting can be carried out concurrently in a one-step process. Use a soft, clean and lint-free cloth in combination with a low-level solution of 70% IsoPropylAlcohol (IPA) to clean and disinfect the device. The product used for cleaning and disinfection must be suitable for both processes (e.g. on the label it should claim that it can be used for both cleaning and disinfection). Moisten the cloth with the alcohol solution and wipe in repetitive movement. Wipe from side to side rather than in a circular motion. For hard-to-reach areas, a cotton swab can be used.

### Drying

Allow the monofilament to air-dry at room temperature. Note that the disinfectant (70% IPA) has the characteristic that it evaporates quickly.

### Maintenance

For Monofilaments there is no need for maintenance (other than Cleaning and Disinfecting - §4 Processing Instructions.)

### Please note:

No process of sterilisation has been validated for these monofilaments. Do not autoclave these devices, use only the type of solution mentioned above and do not expose these devices to extreme environmental conditions, as this may damage the devices and shorten their lifetime.

## 5. Storage, Handling and Transport

These monofilaments should be stored and handled in a clean and dry environment. The devices should be stored, handled and transported in a manner that protects them against moisture, dust, extreme temperatures and humidity.

## 6. General Warnings

This Instruction for Use does not replace adequate training / education of the intended user. The responsibility for proper treatment of the patient and the presence of adequate training/education rests with the qualified intended user. The manufacturer is not responsible for any complications resulting from an incorrect diagnosis, incorrect product selection or improper use of the medical device.

 **This Instruction for Use cannot replace proper training**

 **To be used in contact with intact skin only**

## 7. Reusability / Product life

These monofilaments can be reused provided that they are not damaged and function properly. The life cycle is limited due to damage and normal wear and tear. We do not define the maximum number of times that a monofilament can be used or that it can go through the preparation cycle. The life cycle depends on many factors, including the nature and duration of use, as well as the handling and storage of the devices. Thorough examination and function testing before the next use is the best way to detect and sort non-functioning devices.

## 8. Warranty

The monofilaments from Expert International are free from defects in material and workmanship. All our monofilaments are manufactured to the highest quality standards. As a result, we give a five-year warranty on manufacturing and workmanship on all our monofilaments. A prerequisite for this is that the devices are cleaned and disinfected in the prescribed correct manner and that the devices are used for its intended purpose by a qualified intended user.

## 9. Company details



Medipharchem Nederland B.V.  
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## 10. Complaint handling

Immediately notify Medipharchem Nederland B.V. (importer) by telephone or e-mail of complaints, defects or incidents related to the monofilament. If possible, store the product concerned and return it to Medipharchem Nederland B.V. Complaints about quality defects to packaging, instructions for use or the product itself must be reported to Medipharchem Nederland B.V.: [info@medipharchem.nl](mailto:info@medipharchem.nl)

Should a serious incident occur (in which the product led to serious deterioration of a patient's state of health, or it could pose a public health threat), report it to the importer (Medipharchem Nederland B.V.) and to the competent authority in your country. Competent authority for the Netherlands: [meldpunt@igi.nl](mailto:meldpunt@igi.nl)