Gutta-percha Injection Needle Instruction Manual

1 Product name

Gutta-percha Injection Needle

2. Model

Model	Gauge	Length
20G 22mm	20G	22mm
20G 24mm	20G	24mm
20G 28mm	20G	28mm
23G 24mm	23G	24mm
23G 28mm	23G	28mm
25G 24mm	25G	24mm

3 Product structure and composition

The injection needle is composed of nut, washer, stop collar, sliver needle, damping sleeve and thread protective sleeve.

4 Intended use

It is used in conjunction with MaxFill-G to fill the root canal via injecting the heated and softened gutta-percha into the root canal.

Note: For the gauge of each model please refer to Point 2.

5 Contraindications

5.1 People who are allergic to known natural latex and metals such as stainless steel, silver, copper, ect. are prohibited to use this device.

5.2 The patient with hemophilia is forbidden to use this device.

5.3 The patients or dentists with heart pacemaker are forbidden to use this device.

5.4 Heart disease patients, pregnant women and children should be cautious to use the equipment.

6 Operation method

Install the injection needle on the front end of MaxFill-G and tighten it with the wrench. Turn on MaxFill-G and the heating tube will start heating automatically untill the preset temperature is reached. Pull the trigger, the molten gutta-percha will be extruded from the injection needle. It can be also used in conjunction with vertical pressurizer to fill the root canal.

7 Precautions

7.1 When the injection needle is installed on MaxFill-G, it should be properly tightened and insulated from heat during operation.

7.2 The injection needle is served non-sterile and must be cleaned, disinfected and sterilized before every use. It is recommended to use autoclave. Sterilization procedure: sterilize at 134 ℃ for 4 minutes (5 minutes in EU), vacuum for 3 times, then dry for 15 minutes. Do not use disinfectant with metal corrosive components (such as chlorine), otherwise it will cause permanent damage to the equipment.

7.3 Do not install or remove the injection needle under heating state. Please power off before replace the injection needle.

7.4 When the injection needle is damaged or worn out, please replace it with a new one.

7.5 Do not polish the injection needle.

7.6 Do not pre-bend the root of needle or taper part.

8 Instructions for reprocessing

8.1 Beginning work

Please read these operating instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions. Always keep this instruction close at hand.

To prevent injury to people and damage to property, please heed the corresponding directives.

The instructions in this manual are only applicable to the product which it was delivered with.

8.2 Introduction

- These reprocessing instructions provide instructions for cleaning, disinfection, sterilization and packaging of manufacturer reusable products intended to be reprocessed in medical facilities.
- The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning, disinfecting or sterilizing manufacturer's medical and dental products are based on the potential risk of infection associated with their use.
- It is recommended to use steam sterilization.
- Remember that sterilization or high-level disinfection cannot be achieved unless the elements of the assembly are cleaned first.
- If you find that the reprocessing instructions from the manufacturer seem to be inadequate, please inform manufacturer about those inadequacies.
- We encourage you to report adverse events related to device reprocessing. Report such events directly to manufacturer.

8.3 Reprocessing - Instructions for reusable products

The instructions are binding for the reprocessing of all reusable products (Here after called "products") of manufacturer. When necessary, additional product-specific instructions are included with the product to provide additional information.

⚠ Before use, carefully read the operating instructions of the manufacturer instrument and devices with which the product will be used. Reusable products must be cleaned, disinfected and sterilized prior to first use. They must be replaced after the number of operations specified by the manufacturer. For this product, the maximal number of operations is 50.

8.4 Preperation - Basic principles

8.4.1 It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

8.4.2 Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic. This applies especially with regard to the additional requirements for the inactivation of prions.

Reprocessing procedures have only limited implications to this product. The limitation of the numbers of reprocessing procedures is therefore determined by number of operations specified by the manufacturer. From the processing side there is no maximum number of allowable reprocessing.

⚠ In case of damage the product should be reprocessed before sending back to the manufacturer for repair.

8.4.3 Preparation at the point of use

Disconnect the product. Remove gross soiling of the instrument with cold water (<40 ℃) immediately after use. Don't use a fixating detergent or hot water (>40 ℃) as this can cause the fixation of residuals which may influence the result of the reprocessing process.

Store the products in a humid surrounding.

8.4.4 Transportation

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

8.4.5 Preparation for decontamination

The products must be reprocessed in a disassembled state, as far as possible.

8.5 Pre-Cleaning

Do a manual pre-cleaning, until the products are visually clean. Submerge the products in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.

8.6 Cleaning

Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.

Automated cleaning:

Use a washer-disinfector (WD) meeting the requirements of the ISO 15883 series.

Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:

4 min pre-washing with cold water (<40℃)

emptying

5 min washing with a mild alkaline cleaner at 55° C

emptying

3 min neutralising with warm water (>40℃);

emptying

5 min intermediate rinsing with warm water (>40℃)

emptying

The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).

⚠ Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.

8.7 Disinfection

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).

A disinfection cycle of 5 min disinfection at 93℃ has been validated for the product to achieve an A0 value of 3000.

Drying:

Automated drying:

Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.

8.8 Functional testing, maintenance

Visual inspection for cleanliness of the products and reassembling if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean.

Before packaging and autoclaving, make sure that the products have been maintained acc. to manufacturer's instruction.

8.9 Packaging

Pack the products in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.

8.10 Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/ EN ISO 17665) under consideration of the respective country requirements.

Minimum requirements: 3 min at 134 ℃ (in EU: 5 min at 134℃)

Maximum sterilization temperature: 138℃

Drying time:

For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.

After sterilization:

Remove the product from the autoclave.

Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.

Check that the sterilization wraps or pouches are not damaged.

⚠ Flash sterilization is not allowed on lumen instruments.

⚠ The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization). In such cases, please observe the respective valid standards (EN ISO 14937/ANSI AAMI ISO 14937 or the procedure-specific standard) and verify the suitability and effectiveness in principle of the procedure (if necessary, including investigations on sterilizing agent residue), taking into account the specific product geometry as part of the validation.

8.11 Storage

Storage of sterilized products in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

8.12 Service life

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in aging of the devices. In this case, the number of permissible re-sterilization cycles is 50.

⚠ The use of ultrasound baths and strong cleaning and disinfection fluids (alkaline pH>9 or acid pH<5) can reduce the life span of devices. The manufacturer accepts no liability in such cases.

⚠ The devices may not be exposed to temperatures above 138℃ .

It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

9 Storage

The injection needle should be stored in clean, dry, ventilated, non-corrosive indoor environment with relative humidity of 10%~93%, atmospheric pressure of 70kPa~106kPa, temperature of -20 ℃ ~+40 ℃ . Do not mix the needle with toxic, corrosive, flammable and explosive materials while storage.

10 Standard icons

Icon	Description
	Consult instructions for use
	Caution
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community
	For indoor use only
	Sterilizable in a steam sterilizer (autoclave) at 134°C
	Caution, hot surface
	Atmospheric pressure limitation: 70kPa-106kPa
	Temperature limit: -20°C ~ +40°C
	Humidity limitation: 10% ~ 93%
	Keep dry
	Fragile, handle with care

Service life: one year

Guilin Refine Medical Instrument Co., Ltd.
No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R. China
Tel: +86-773-7796686 Email:refine@refine-med.com
Website: http://www.refine-med.com

EC REP MedNet EC-REP GmbH
Borkstrasse 10 · 48163 Muenster · Germany

RF-ING-M001-1.0 Modify: 2022-01