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CE
1639



EU REP

Stoddard ApS, Moellegade 32
8000 Aarhus C, Denmark



CH REP

EUMEDIQ AG, Grafenauweg 8,
6300 Zug, Switzerland

Sterilisation and Instructions for Use Classification: Class 2a Medical Device – Single Use Devices

GMDN	Medical Device	Basic UDI-DI
64015	<p><u>Prophy Brushes</u> JC/WNRA, JC/WNSC, JC/XWNRA, JC/WBRA, JC/WBSC, JC/PKNRA, JC/PUNRA, JC/PBNRA, JC/SBNRA, JC/GNRA, JC/YNRA, JC/ORNRA, JC/PKNSC, JC/PUNSC, JC/PBNSC, JC/SBNSC, JC/GNSC, JC/YNSC, JC/WNGRA, JC/WNGSC, KS/WNRA001, KS/WNRA002, KS/WNSC001, KS/WNSC002, KS/WBRA001, KS/WBRA002, KS/WBSC001, KS/WBSC002, KS/BBRA001, KS/BBRA002, KS/BBSC001, KS/BBSC002, KS/BNSC001, KS/PKNRA001, KS/PKNRA002, KS/PUNRA001, KS/PUNRA002, KS/PBNRA001, KS/PBNRA002, KS/ORNRA001, KS/ORNRA002, KS/YNRA001, KS/YNRA002, KS/PKNSC001, KS/PKNSC002, KS/PUNSC001, KS/PUNSC002, KS/PBNSC001, KS/PBNSC002, KS/YNSC001, MT/XWNRA, MT/PKNRA, MT/PUNRA, MT/PBNRA, MT/SBNRA, MT/GNRA, MY/YNRA, MT/XWNSC, MT/PKNSC, MT/PUNSC, MT/PBNSC, MT/SBNSC, MT/GNSC,</p>	5051717DP01TU
46938	<p><u>Prophy Cups</u> PRA001, PRA002, PRA003, PSRA001, PSRA002, PSRA003, PSRA004, PSRA005, PSRA011, PSRA012, PSRA013, PSRA015, PSRA017, TPY002G, EPR003, EPY002, EPY003A, PSC001, PSC002, PSC003, PSC004, PSC005, PSC011, PSC012, PSC013, PSC014, PSC015XH, PSC018, PSC020, EPR002A, PSO001, PSO002, PSO003, PSO004, PSO005, PSO011, PSO012, PSO013, PSO015, PSO019, PSO020, PSO021, PSO022, PSO023, PSO028, EPR004A, PSMRA001, PSMRA002, PSMRA003, PSMSC001, PSMSC002, PSMSC003, EPY004, EPY005, TPR002A, TPR002H, TPR003, TPY002, TPY003A</p>	

The Class 2a medical devices are for use in the mouth by or under the instruction of a qualified dental professional and are manufactured in accordance with the standard ISO 1797 and should only be used in conjunction with a rotary hand piece that conforms to ISO 14457. The operator should ensure that the rotary instrument is correctly installed in the hand piece prior to commencement of any procedure.

The devices are sold non-sterile and must be cleaned and sterilised by a qualified dental professional prior to use. Sterilisation validation testing is carried out on a wide range of devices representative of those in common use in dental practice and selected to offer a “worst case” with respect to ease of cleaning. The validation of the sterilisation process has been performed by Test Labs Limited, UK, PE3 8SB.

– Reprocessing Validation Report (ref. PR-24-TL-0232 dated December 2024).

STERILISATION

SCOPE

These instructions are applicable to the processing of Stoddard dental rotary instruments before first use. The dental rotary instruments are supplied mechanically clean but are not sterile. They should, therefore, be sterilised before use. These are single use devices, and the instructions therefore only apply to processing before first, single use.

Sterilisation and Instructions for Use

CONTAINMENT AT THE POINT OF USE

Unless there is specific infection or cross-contamination risks, there are no special requirements for containment. The instruments can be transported wet or dry and should be protected from damage to the working part. If transported wet, there is an increased chance of staining or corrosion. Prolonged storage in disinfectant solutions may result in corrosion and should be avoided.

Delay in processing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.

PREPARATION FOR CLEANING

There are no special requirements unless infection controls require the use of a disinfectant, in which case a disinfectant agent validated for processing of dental rotary instruments must be used and the disinfectant manufacturers' instructions must be followed.

PRE-CLEANING

As preparation before automated cleaning, any visible debris from the devices should be removed with a disposable cloth for at least 10 seconds with neutral enzymatic detergent.

The devices should be placed in a sonic bath using distilled water for 5 minutes to dislodge residues with high-frequency sound waves, and after sonication all devices should be rinsed with purified water.

CLEANING

Auto cleaning is the only recommended method and should use only validated washer disinfectors and appropriate agents validated for use on the instruments with the selected machine. Follow the washer disinfectant and the cleaning agent manufacturers' instructions.

DRYING

Dry the instruments using paper towelling.

INSPECTION

Inspect the instruments, with the aid of magnification if necessary, and discard any damaged or corroded instruments.

PACKAGING FOR STERILISATION

If using a **vacuum autoclave** pack the instruments in dedicated instrument trays or pouches validated for sterilisation.

If using a **non-vacuum autoclave**, the instruments should not be packed or wrapped but be contained in dedicated stands with perforated lids.

NOTE: National legislation may require that the instruments are wrapped in pouches for processing in either type of autoclave.

STERILISATION

Autoclave the instruments for a holding time of not less than three minutes at a temperature of 134°C.

The holding time is the minimum time for which the minimum temperature is sustained.

The autoclave manufacturer's instructions must be followed. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.



(In the absence of a harmonised standard symbol for sterilisation, Stoddard Manufacturing Company Ltd use a generally accepted symbol on the labels as shown adjacent.)

STORAGE

The instruments should be stored in the sterilisation container (stand or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents with water. Storage should be in dry, clean conditions and at ambient temperature (18°C-30°C).

Sterilisation and Instructions for Use

VALIDATION

These processes have been validated as being capable of preparing Stoddard dental instruments for use. It remains the responsibility of the processor to ensure that the processing as performed using the equipment, materials and personnel achieve the required results. This may require validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

INSTRUCTIONS FOR USE

- The instruments are for single use only. Do not reuse.
- Inspect the device prior to use for any defects.
- Only use hand piece, angles and turbines that are technically and hygienically flawless, maintained and cleaned.
- Ensure handpieces are maintained in good working order and remain adequately lubricated at all times to ensure maximum effectiveness of the device. Failure to properly maintain the handpiece can lead to procedural delays, injury to the user or patient, aspiration or swallowing of the device or damage to the preparation site.
- The device and hand piece must be concentric and true running. Instruments that are deformed or no longer run true should not be used and must be disposed of.
- The instruments must be fully inserted into the handpiece and locked where applicable.
- The instruments are to be brought to speed before placing on the object.
- Polish with gentle circular movements.
- Avoid tilting or levering because of the increased risk of breakage.
- Any damaged and incorrectly shaped instruments will cause vibration. Bent or non-concentric instruments must be disposed of.
- Instruments that are deformed or no longer run true should not be used and must be disposed of.
- Wear eye protection.
- Wear a respiratory mask to prevent inhaling any dust and/or debris during the procedure.
- These products must only be used by qualified dental professional.
- Incorrect use produces poor results and increases risk.
- Incorrect use may harm tissue, cause premature wear, destroy the instrument and endanger the operator, patient or third parties.
- The devices are designed and manufactured to perform safely when used in combination with CE marked medical devices (i.e. prophylaxis paste or mandrels if required) which are themselves intended for use in the oral cavity.
- Keep dry
- Keep away from sunlight

Snap-On devices

- To ensure vibration-free working the connected instrument must be centred after mounting on the mandrel or shaft. Any damaged and incorrectly shaped instruments will cause vibration. Bent or non-concentric instruments must be disposed of.
- Snap-On brushes and polishers are to be used with mandrel Ref: TPR010 or equivalent. Mandrels and brushes or polishers are proven to function together correctly by historical use with no adverse reports.

PRESSURE

Avoid excessive pressing force!

- Excessive pressure must be avoided at all times.
- Excessive pressure may damage the working sections of rotary polishing instruments or damage the fill material. Heat build-up is increased.

Sterilisation and Instructions for Use

RECOMMENDED SPEEDS

- Maximum speed 10,000 rpm
- Keep within the speed range of 1,500 – 10,000 rpm

- Never exceed the maximum permitted speed of the product. The recommended speeds and maximum permitted speeds vary from product to product. Always check the recommended speed as stated on the packaging.
- If you exceed the maximum permitted speed, the instrument tends to vibrate, which may cause damage to the shaft and/or make the instrument break, with a risk to the user, the patient or third parties. Failure to comply with the maximum permitted speed produces an increased safety risk.
- Keep within the speed range of the product being used for the best work results and to increase the service life of the instrument.
- Failure to comply with the maximum permitted speed produces an increased safety risk.

INTENDED PATIENT GROUPS/INTENDED PURPOSE

The devices are intended for use on patients of any age. The products are a tool for use by the qualified dental professional who is responsible for determining the treatment required by each individual patient.

The final device selection will be dependent on 3 factors:

- the dental professional performing the procedure,
- the patient undergoing treatment,
- the type of procedure being performed.

INTENDED USERS

All devices are intended to be used by a qualified dental professional.

INTENDED USE AND INDICATIONS

The devices are used for a wide range of procedures, including the cleaning and polishing of natural teeth, gold and amalgam fillings, composites, compomers and glass ionomer cements for removing plaque and stains.

In accordance with the Medical Device Regulation 2017/745, these devices are invasive through the body orifice not beyond the larynx, are not implantable and are intended for transient use. The area of contact within the mouth is the teeth.

There are no claims made by the manufacturer other than for dental procedure.

LIFETIME OF THE DEVICE

The lifetime of the device depends on a number of factors and actions being carried out by the end user including:-

- the correct procedures being followed for sterilisation of the device prior to use,
- the instructions for use being followed correctly to avoid damage occurring to the instrument and/or patient,
- the condition of the handpiece being used,
- possible solutions being used with the product,
- the device being inspected for defects following preliminary cleaning.

Sterilisation and Instructions for Use

SHELF LIFE & USE BY DATE

A 10 year lifespan has been concluded from the inspection tests for dimensional checks, mandrel critical connection checks and shelf life tests conducted on products over 10 years old and the product performing correctly and without failure demonstrating the 10 year shelf life is acceptable.

Stoddard products are tested and certified as both safe and usable within the date parameters set by the use by dates as indicated on the product labelling. Whilst we would not expect any real degradation of the product, we cannot guarantee its safety beyond the use by date and would strongly recommend that the products are disposed of in accordance with the local regulations. The use by date set for these devices is 5 years from the date of packing.

Stoddard products are manufactured and packaged in such a way that no deterioration can occur which could compromise the safety of the patient, user or other persons or the performance of the product.

SAFETY PRECAUTIONS
























These dental instruments were developed and manufactured for their specific dental surgical application. Incorrect use may harm tissue, cause premature wear, destroy the instrument and endanger the operator, patient or third parties.

WARNINGS

Used rotary instruments should be considered as contaminated and appropriate handling precautions should be taken. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient.

CONTRAINDICATIONS

These devices contain small amounts of nickel or are covered in nickel plating and should, therefore, not be used on individuals with a known sensitivity to this metal as in extreme cases it may cause hypersensitivity.

	Manufacturer		Importer		Distributor		NB Number
	Date of manufacture		Instructions for Use		Autoclave		Contains biological material of animal origin
	Authorised Representative		Lot number		Quantity		Use by date
	Swiss Authorised Representative		Product Reference		Eye Protection		Maximum rpm
	Medical Device		Single use only - do not re-use		Keep away from sunlight		Keep dry
	Ultrasonic Bath						
	(01) 05051717999991 (10) 123456 (17) 300601	UDI	(01) GTIN / UDI-DI (10) PI (LOT No.) (17) PI (Expiry Date)		Unique Device Identifier		