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CE
1639
MD

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

GMDN Code	GMDN Term	Basic UDI-DI	Medical Device	MD Class
64015	Dental Professional Prophylaxis Brush, single use	5051717DP01TU	JC, Junior Cup Brushes	IIa
	Dental Professional Prophylaxis Brush, single use		KS, KSO, MT Brushes	IIa
46938	Dental Polishing Cup, single use		Prophy Polishers	IIa

The Sterilisation and Instructions for Use are for single use medical devices and only covers the products listed in the relevant product group schedules.

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 the qualified dental professional prior to use. The validation of the sterilisation process has been performed by The University of Liverpool, Clinical Dental Sciences Department, UK, L69 3BX reference – Issue No. 1278 dated December 2003. This study and report were initiated and authorised by the British Dental Trade Association (BDIA).

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.

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.

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 disinfector 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 134ºC.

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.

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

<u>Snap-On devices</u>

- 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. Stoddard 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.

RECOMMENDED SPEEDS

<u>Junior Cup Brushes, Microtuft and Pencil Brushes One Knot</u>

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

<u>Prophy Cups, Right Angle, Screw and Snap-On</u>

- 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 Directive 93/42/EEC and 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 maximum number of repeat applications required is determined by the qualified dental professional. 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 is normally determined by wear and tear and not through re-processing and 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.

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 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 manufacture. The 5 year shelf life has been concluded from the inspection tests for dimensional checks, shank/mandrel critical connection checks and shelf life tests conducted on products over 5 years old and the product performing correctly and without failure demonstrating the 5 year shelf life is acceptable.

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

CE NB Number


Date of manufacture


Instructions for Use

Autoclave

Contains biological material of animal origin

EC REP Authorised Representative

LOT Lot number


Quantity


Use by date

CH REP Swiss Authorised Representative

REF Product Reference


Eye Protection

rpm Maximum rpm

MD Medical Device


Single use only - do not re-use


Keep away from sunlight


Keep dry


(01)05051717145268
(10) 123456
(17) 260920
UDI
(01) GTIN / UDI-DI
(10) PI (LOT No.)
(17) PI (Expiry Date)

UDI Unique Device Identifier