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CE 1639

MD

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

GMDN Code	GMDN Term	Basic UDI-DI	Medical Device	MD Class
64617	Dental Abrasive Disk, single use	5051717ABP1TW	Maxflex Discs	IIa

MFD200	Maxflex Snap-On dental polishing disc, coarse, 10mm
MFD204	Maxflex Snap-On dental polishing disc, coarse, 14mm
MFD201	Maxflex Snap-On dental polishing disc, medium, 10mm
MFD205	Maxflex Snap-On dental polishing disc, medium, 14mm
MFD202	Maxflex Snap-On dental polishing disc, fine, 10mm
MFD206	Maxflex Snap-On dental polishing disc, fine, 14mm
MFD203	Maxflex Snap-On dental polishing disc, ultra-fine, 10mm
MFD207	Maxflex Snap-On dental polishing disc, ultra-fine, 14mm
SET1013	Maxflex Snap-On Set
MFD118	Maxflex Pop-On dental polishing disc, super coarse, 10mm
MFD119	Maxflex Pop-On dental polishing disc, super coarse, 14mm
MFD100	Maxflex Pop-On dental polishing disc, coarse, 10mm
MFD104	Maxflex Pop-On dental polishing disc, coarse, 14mm
MFD101	Maxflex Pop-On dental polishing disc, medium, 10mm
MFD105	Maxflex Pop-On dental polishing disc, medium, 14mm
MFD102	Maxflex Pop-On dental polishing disc, fine, 10mm
MFD106	Maxflex Pop-On dental polishing disc, fine, 14mm
MFD103	Maxflex Pop-On dental polishing disc, ultra-fine, 10mm
MFD107	Maxflex Pop-On dental polishing disc, ultra-fine, 14mm
SET1014	Maxflex Pop-On Set

Grit Size	Maximum RPM
Super Coarse	10,000 rpm
Coarse	10,000 rpm
Medium	10,000 rpm
Fine	30,000 rpm
Ultra-fine	30,000 rpm

The 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.

STERILISATION

- The discs do not require sterilisation. The rotary instrument should be kept in its original packaging at room temperature and protected against dust and moisture until used for the first time.

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

STORAGE
The instruments should be stored in the 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.
- 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.
- Do not use the discs at speeds in excess of the recommended RPM.
- Do not operate the mandrel without the disc attached
- Avoid touching composite with the mandrel or disc eyelet because discolouration may occur. This discolouration can be removed by repetition of the polishing steps. The smaller, low profile, mandrel head and unique eyelet design reduces this risk of composite and eyelet contact.
- Use the discs in the correct order, incorrect procedures can result in a reduction in the polishing quality.
- Keep dry
- Keep away from sunlight

Snap-On and Pop-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 and Pop-On discs are to be used with mandrel Ref: CTP061, CTP062 or equivalent. Stoddard mandrels polishing discs 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.

INSTRUCTIONS/RECOMMENED SPEEDS

1) Always use Stoddard discs when attached to a mandrel with a slow speed hand piece (maximum 10,000 or 30,000 RPM). Affix the disc to the mandrel by gently pushing the eyelet piece on to the mandrel until the disc is securely in place.
2) The polishing motion should be constant and uni-directional, e.g. commencing at the gingiva and moving outwards over the restoration. A back and forth movement over the composite – enamel margin is not recommended.
3) Use light pressure when polishing, let the discs do the work.
4) Keep the restoration surface and disc dry while polishing. A dry surface will produce a smoother, more uniform surface.
5) Remove Stoddard Maxflex discs from the mandrel by: -
   A) positioning a thumbnail under the disc eyelet portion and pushing the disc away from the hand piece (i.e. Pop off) or;
   B) grasping the disc and eyelet and peeling the disc upwards away from the handpiece.

INTENDED PATIENT GROUPS/INTENDED PURPOSE
The devices are intended for use on patients of any age. The products are only aimed as a tool for use by the qualified dental professional who is responsible for determining the treatment required by each individual patient and which treatment would outweigh the risks of performing.

The final brush 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
Maxflex Pop on and Snap on discs when attached to RA mandrels are for used for finishing and polishing of composite restorations, gold and amalgam. The discs are produced in 2 different shapes and 5 different grits and give best performance when applied at slow speed (either at maximum of 10,000 or 30,000 RPM dependant on the grit size), under slight pressure.

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 the cleaning of teeth and improved dental hygiene.

LIFETIME OF THE DEVICE
The lifetime of the device is normally determined by wear and tear and depends on a number of factors and actions being carried out by the end user including:-

- 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 routinely inspected for defects before any procedure

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


Quantity


Use by date

EC REP Authorised Representative

LOT Lot number


Eye Protection

rpm Maximum rpm

MD Medical Device

REF Product Reference


Keep away from sunlight


Keep dry


Single use only - do not re-use


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

UDI Unique Device Identifier