

Instructions for Use

Classification: Class 1 Medical Device – Single Use Devices

GMDN Code	GMDN Term	Basic UDI-DI	Medical Device	MD Class
35702	Dental Abrasive Strip, single use	5051717MF02UB	Maxflex Strips	I

MFS001 Maxflex Strip – coarse/medium grit, blue/purple
MFS002 Maxflex Strip – fine/ultra-fine grit, pink/white

Grit Size	FEPA Ref	Size (Micron)	Colour
Coarse/Medium	F180	63	Blue
	F320	29.2	Purple
Fine/Ultra-fine	F400	17.3	Pink
	F800	6.5	White

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

INTENDED USE AND INDICATIONS

Maxflex Strips are used by the Dental Surgeon for the finishing and polishing of composite restorations. The strips are produced in 2 different strips comprising of 4 different grits and give best performance when applied under slight pressure.

STERILISATION

- The strips do not require sterilisation. The strips should be kept in their original packaging at room temperature and protected against dust and moisture until used.

STORAGE

The strips should be kept in hygienic stands, dishes or other suitable containers and they must be protected against dust, moisture and contamination during storage. If the strips are not used right away, it is advisable to keep them in their original packaging.

PROPER USE

- Products that are deformed should not be used and must be disposed of.
- Use the strips in the correct order, incorrect procedures can result in a reduction in the polishing quality.
- Wear a face mask to prevent biological transfer.
- Incorrect use produces poor results and increases the risk. These products must only be used by qualified staff.
- Keep dry
- Keep away from sunlight

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PRESSURE

- Excessive pressure must be avoided at all times.
- Excessive pressure may cause heat build up which may damage the strip.

Excessive pressure may cause overheating, which injures the pulp. In extreme cases, the instrument may even fracture.

INSTRUCTIONS

- 1) Insert the central section (the area without abrasive) of the finishing strip between contact points.
- 2) Position the selected portion of the strip over the composite surface to be finished.
- 3) Firmly grasp both ends of the strip and draw the abrasive over the composite in a vigorous, back and forth motion
- 4) Repeat procedure using another grade of the strip.
- 5) Discard strip.
- 6) Repeat steps 1-5 with Stoddard Polishing strips.

DISPOSE OF WORN INSTRUMENTS

- Fractured and incorrectly shaped strips can cause injury.

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 instruments and endanger the operator, patient or third parties.

WARNINGS

Used dental 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

No known contraindications.



Manufacturer



Importer



Distributor



NB Number



Date of manufacture



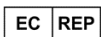
Instructions for Use



Quantity



Use by date



Authorised Representative



Lot number



Eye Protection



Keep dry



Medical Device



Product Reference



Keep away from sunlight



Single use only - do not re-use



(01)05051717145268
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UDI

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



Unique Device Identifier