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PRODUCT SAFETY DATA SHEET

Product: Prophylaxis Polishing Cups Latex Free RA Shanks

Classification: Class 2a Medical Device

Schedule of Products (Ref):

PRA001	Prophy Polishing Cup, Pink, 6 web, latex free, RA shank
PRA002	Prophy Polishing Cup, Purple, 6 web, latex free, RA shank
PRA003	Prophy Polishing Cup, Blue, 6 web, latex free, RA shank
PRA004	Prophy Polishing Cup, White, 6 web, latex free, RA shank
PRA005	Prophy Polishing Cup, Yellow, 6 web, latex free, RA shank
PSRA001	Prophy Polishing Cup, Pink, 6 web with skirt, latex free, RA shank
PSRA002	Prophy Polishing Cup, Purple, 6 web with skirt, latex free, RA shank
PSRA003	Prophy Polishing Cup, Blue, 6 web with skirt, latex free, RA shank
PSRA004	Prophy Polishing Cup, White, latex free, RA shank
PSRA005	Prophy Polishing Cup, Yellow, latex free, RA shank
PSRA011	Prophy Polishing Cup, Pink, 4 web and ribbed with skirt, latex free, RA shank
PSRA012	Prophy Polishing Cup, Purple, 4 web and ribbed with skirt, latex free, RA shank
PSRA013	Prophy Polishing Cup, Blue, 4 web and ribbed with skirt, latex free, RA shank
PSRA014	Prophy Polishing Cup, Blue, 4 web and ribbed, latex free, RA shank
PSRA015	Prophy Polishing Cup, Yellow, 4 web with skirt, latex free, RA shank
PSRA016	Prophy Polishing Cup, Orange, 4 web with skirt, latex free, RA shank
PSRA017	Prophy Polishing Cup, Green, 4 web with skirt, latex free, RA shank
TPY002G	Prophy Polishing Cup, White, 4 web with skirt, latex free, RA shank
EPR003A	Prophy Polishing Cup, White, 6 web, latex free, RA plastic shank
EPR003	Prophy Polishing Cup, White, 6 web with washer, latex free, RA shank
EPY002	Prophy Polishing Cup, White, 4 web and ribbed with skirt, latex free, RA shank
EPY003A	Prophy Polishing Cup, White, 6 web with skirt, latex free, RA shank

Single use device: For the prophylaxis polishing of natural teeth, please consult Sterilisation and Instructions for use.

Description: Stoddard prophylaxis polishing cups and points are two component products produced by moulding a latex free, synthetic polymer to metal shanks.

Component 1: Synthetic Elastomer (Polymer) – (100 % latex free)

This material may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

Physical data:

Physical state:	Solid
Solubility in water:	Insoluble
Evaporation rate:	Not applicable
Specific gravity, (working part):	1.28
Colour (working part):	Pink, Purple & Blue
Odour (working part):	Mild
Evaporation rate:	Not applicable
Solubility in water:	Insoluble

Component 2: Metal Shanks (brass - nickel plated) RA Shank.

These materials may also contain trace elements, which are non-hazardous or non-hazardous at the levels of inclusion.

Physical data:

Physical state:	Solid
Solubility in water:	Insoluble
Evaporation rate:	Not applicable
Specific gravity (working part):	1.28
Specific gravity shank:	Not applicable
Colour (working part):	White/grey
Colour shank:	Bright metallic
Odour (working part):	Mild
Odour shank:	None
Evaporation rate:	Not applicable
Solubility in water:	Insoluble

Warning: For professional use only. This instrument is for use by or under the supervision of a qualified dental professional. This instrument is manufactured in accordance with standard ISO 1797 should only be used in conjunction with rotary hand pieces that conform with ISO 14457. The operator must ensure that this instrument is correctly installed in the hand piece prior to commencement of procedure. This product is recommended for use with Stoddard prophylaxis paste.

Rotational speed: Max 10,000 RPM

Single use device - Sterilisation: This instrument should be sterilised before single use, autoclave using a validated procedure, please consult Sterilisation and Instructions for use.

Storage: Store in clean dry conditions at ambient room temperature away from light. Following sterilisation these instruments should be stored in the sterilization container (bur stand or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents with water.

Personal protection equipment:

Eyes:	The wearing of safety glasses is recommended during use.
Gloves:	May be worn during clinical procedure.
Face mask:	May be worn during clinical procedure.

Health hazard information:

Ingestion:	Accidental ingestion is not harmful, consult physician if necessary.
Contamination of single use device:	Do not re-use, sterilise before single use, consult Sterilisation and Instructions for use.

First aid measures (in case of):

Inhalation:	Not respirable. If swallowed, the buccal cavity and airway should be cleared and the instrument removed. If necessary a physician should be consulted.
Allergy:	No allergic reaction to these products has been reported to the company. In case of a specific allergy or permanent irritation, consult physician.
Contact with eyes:	In case of accidental contact with the moving instrument consult physician.

Fire and explosion data:

Extinguishing media:	Atomised water jet, carbon dioxide foam, dry chemicals.
Special fire fighting instructions:	None

Hazardous reactivity:

Stability:	Stable
Incompatibility:	Strong acids, oxidising agents.

Product Safety Data Sheets

Waste disposal procedures:

Used rotary instruments should be considered as contaminated and appropriate handling precautions should be taken following a clinical procedure and during disposal. Gloves, eye protection and a mask should be worn. Handling, storage, transportation and disposal are generally performed similarly to those of other biological wastes designated by the national or local government regulations. Incinerate or landfill in compliance with local and national regulations.

Transportation:

The product should be transported in original containers to avoid damage or leakage. Keep containers dry.

Articles as defined in OSHA Hazard Communication Standard, Section 1910.1200

These instruments are considered manufactured "articles" and, as such are exempt from Product Safety Data Sheet requirements. These products are considered non-hazardous when used according to accepted practices for the intended use. As a courtesy to our customers this document is to provide basic guidance for safe handling, use, storage, transportation and disposal. The information is not to be considered a warranty or detailed quality specification and relates only to the specific instrument and materials designated herein and not to its use in combination with any other materials or in any process.

The materials contained in this product are non-hazardous or non-hazardous at the levels of inclusion.

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The information in this PSDS was obtained from sources, which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This PSDS was prepared and is to be used only for this product. If the product is used as a component in another product, this PSDS information may not be applicable.

Emergency Phone No: (0044) 1462 686221