

MEDICAL DEVICE**TECHNICAL DATA SHEET**

POLO MB OISTERWIJK BV

Product name: PoloDent Prophy Brushes Cup White Nylon RA

Product specification

Product name:	PoloDent® Prophy Brushes Cup White Nylon RA
Article number(s):	74 36 25
CE Class:	Ila Medical Device
Company:	Polo MB Oisterwijk BV Laarakkerweg 5 5061 JR Oisterwijk The Netherlands www.polodent.com

Description

The Dental surgeon or Hygienist uses PoloDent Junior Cup brushes for the prophy cleaning or polishing of natural teeth and filled surfaces in the mouth. They are generally 4-component products filled with nylon based filaments.

Component 1: Metal Shank Ferrule (Brass) Right Angle (RA) and Screw Type (SC) (1.72 universal thread)**Description**

Turned and fine ground mandrels made from free cutting brass rod JIS H3250 C3604 BD, or CUZN39PB3 or similar grade specification with Right Angle shanks produced to conform dimensionally with ISO1797 and Screw type shanks are produced to M1.8 x 0.35 DIA 1,70/1,78 universal type thread.

The strength of the alloy used in these devices has been selected for good tensile strength in combination with mechanical hardness. Proof of the suitability and durability of these materials is borne out by the exemplary performance record over a considerable number of years. There is no evidence of a shank failure due to material selection during this time. PoloDent brushes are proven to function together correctly by historical use with no adverse reports.

Raw Material Composition

(Approximate, varies between grades)

Chemical Analysis	%	CAS Number
Copper – Cu	57.0 to 59.0%	7440-50-8
Cadmium – Cd	Max 0.0075%	7440-43-9
Iron – Fe	0.1 to 0.3%	7439-89-6
Lead – Pb	2.5 to 3.5%	7439-92-1
Nickel – Ni	0.04 to 0.3%	7440-02-0
Tin – Sn	0.2 to 0.3%	7440-31-5
Zinc – Zn	Balance	7440-66-6
Aluminium – Al	Max 0.05%	7429-90-5

Material hardness

Vickers:	HV151, megapascal 510MPa.
Surface Treatment:	Bright Nickel Plated (Ni) Test Result 99.97% CAS Number 7440-02-0

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

Physical Data

Physical state:	Solid
Colour:	Natural bright metallic.
Odour:	None
Evaporation rate:	Not applicable.
Specific gravity:	Not applicable.
Solubility in water:	Insoluble

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Fire and explosion data

Flash point (method):	Not applicable.
Flash ignition temp:	Not applicable.
Extinguishing media:	Water, carbon dioxide, dry chemicals.
Special fire fighting instructions:	None

Hazardous reactivity

Stability:	Stable
Conditions to avoid:	Heating above 340°C
Incompatibility:	Strong acids, oxidising agents.

Health hazard information

Brass in solid wire form is not hazardous to health. Do not use in a case of a specific allergy.

Ingestion:	Not a probable route of exposure.
Inhalation:	Not respirable.

Stability and reactivity

Chemical stability:	Stable at normal temperature and storage conditions.
Incompatibility with other materials:	None reasonable or foreseeable.
Hazardous decomposition products:	Decomposition will not occur.

Hazardous polymerisation

Polymerisation will not occur.

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Product name:
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Component 2a: Junior Cup Ferrule Brass Cup, Nickel Plated

Description

The component part Cup Ferrule is a metal pressing composed of brass CuZn30 and surface treatment bright nickel-plated.

Raw Material Composition

(Approximate, varies between grades)

Compounds	%	CAS Number
Copper – Cu	69.00 – 71.00 %	7440-50-8
Tin – Sn	0.00 – 0.02 %	7440-31-5
Iron - Fe	0.00 – 0.05 %	7439-89-6
Aluminium – Al	0.00 – 0.02 %	7429-90-5
Zinc - Zn	Remainder	7440-66-6
Nickel - Ni	0.00 – 0.10 %	7440-02-0
Lead – Pb	0.00 – 0.02 %	7439-92-1

Surface Treatment: Bright Nickel Plated (Ni) Test Result 99.97%, 1.0 – 2.0 microns. CAS Number 7440-02-0

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

Physical Data

Physical state:	Solid
Colour:	Natural bright metallic.
Odour:	None
Evaporation rate:	Not applicable.
Specific gravity:	Not applicable.
Solubility in water:	Insoluble

Fire and explosion data

Flash point (method):	Not applicable.
Flash ignition temp:	Not applicable.
Extinguishing media:	Water, carbon dioxide, dry chemicals.
Special fire fighting instructions:	None

Hazardous reactivity

Stability:	Stable
Conditions to avoid:	Heating above 340°C
Incompatibility:	Strong acids, oxidising agents.

Health hazard information

This instrument is not considered hazardous to health. Do not use in a case of a specific allergy.

Ingestion:	Accidental ingestion is not harmful or a probable route of exposure.
Inhalation:	Not respirable.
Allergy:	Low risk from transient use.

Stability and reactivity

Chemical stability:	Stable at normal temperature and storage conditions.
Incompatibility with other materials:	None reasonable or foreseeable.
Hazardous decomposition products:	Decomposition will not occur.

Hazardous polymerisation

Polymerisation will not occur.

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Component 2b: Junior Cup Ferrule Brass Cup, Nickel and Gold plated

Description

The component part Cup Ferrule is a metal pressing composed of brass CuZn30 and surface treatment bright nickel-plated covered with Gold plate.

Raw Material Composition

(Approximate, varies between grades)

Compounds	%	CAS Number
Copper – Cu	69.00 – 71.00 %	7440-50-8
Tin – Sn	0.00 – 0.02 %	7440-31-5
Iron - Fe	0.00 – 0.05 %	7439-89-6
Aluminium – Al	0.00 – 0.02 %	7429-90-5
Zinc - Zn	Remainder	7440-66-6
Nickel - Ni	0.00 – 0.10 %	7440-02-0
Lead – Pb	0.00 – 0.02 %	7439-92-1

Surface Treatment: Bright Nickel Plated (Ni) Test Result 99.97%, 1.0 – 2.0 microns. CAS Number 7440-02-0, covered with decorative Gold plating, CAS Number 7440-57-5.

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

Physical Data

Physical state:	Solid
Colour:	Natural Golden metallic.
Odour:	None
Evaporation rate:	Not applicable.
Specific gravity:	Not applicable.
Solubility in water:	Insoluble

Fire and explosion data

Flash point (method):	Not applicable.
Flash ignition temp:	Not applicable.
Extinguishing media:	Water, carbon dioxide, dry chemicals.
Special fire fighting instructions:	None

Hazardous reactivity

Stability:	Stable
Conditions to avoid:	Heating above 340°C
Incompatibility:	Strong acids, oxidising agents.

Health hazard information

Brass in solid wire form is not hazardous to health. Do not use in a case of a specific allergy.

Ingestion:	Not a probable route of exposure.
Inhalation:	Not respirable.
Allergy:	Low risk from transient use.

Stability and reactivity

Chemical stability:	Stable at normal temperature and storage conditions.
Incompatibility with other materials:	None reasonable or foreseeable.
Hazardous decomposition products:	Decomposition will not occur.

Hazardous polymerisation

Polymerisation will not occur.

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Component 3: Junior Ring**Description**

The component part Junior Ring is a metal pressing composed of brass CuZn37.

Raw Material Composition

(Approximate, varies between grades)

Compounds	%	CAS Number
Copper – Cu	62.00 – 64.00 %	7440-50-8
Tin – Sn	0.00 – 0.1 %	7440-31-5
Iron - Fe	0.00 – 0.1 %	7439-89-6
Aluminium – Al	0.00 – 0.05 %	7429-90-5
Zinc - Zn	Remainder	7440-66-6
Nickel - Ni	0.00 – 0.30 %	7440-02-0
Lead – Pb	0.00 – 0.1 %	7439-92-1

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

Physical Data

Physical state:	Solid
Colour:	Natural metallic.
Odour:	None
Evaporation rate:	Not applicable.
Specific gravity:	Not applicable.
Solubility in water:	Insoluble

Fire and explosion data

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

Hazardous reactivity

Stability:	Stable
Incompatibility:	Strong acids, oxidising agents.

Health hazard information

Components not considered hazardous to health. Do not use in a case of a specific allergy.

Ingestion:	Accidental ingestion is not harmful or a probable route of exposure.
Inhalation:	Not respirable.
Allergy:	Low risk from transient use.

Stability and reactivity

Chemical stability:	Stable at normal temperature and storage conditions.
Incompatibility with other materials:	None reasonable or foreseeable.
Hazardous decomposition products:	Decomposition will not occur.

Hazardous polymerisation

Polymerisation will not occur.

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Product name: PoloDent Prophy Brushes Cup White Nylon RA

Component: Fill material

Material Description

Nylon filament.

Specification

Chemical name: Polyhexamethylene Dodecanamide (Nylon 6.12)
CAS No. 26098-55-5
Less than 1% colorants.

Physical Data

Melting point: 208-215°C
Boiling point: Not applicable.
Solubility in water: Insoluble.
Evaporation rate: Not applicable.
Specific gravity: 1.05-1.07

Fire and explosion data

Flash point (method): Not applicable.
Flash ignition temp: 400°C (ASTM D1929)
Extinguishing media: Water, carbon dioxide, dry chemicals.
Special fire fighting instructions: None

Health hazard information

Nylon is not a hazardous material. Do not use in a case of a specific allergy.

Ingestion: Not a probable route of exposure.
Inhalation: Not respirable.
Allergy: Low risk from transient use.

Hazardous reactivity

Stability: Stable
Conditions to avoid: Heating above 340°C
Incompatibility: Strong acids, oxidising agents.
Decomposition products: Carbon monoxide, ammonia, aldehydes.

Stability and reactivity

Chemical stability: Stable at normal temperature and storage conditions.
Incompatibility with other materials: None reasonable or foreseeable.
Hazardous decomposition products: Decomposition will not occur.

Hazardous polymerisation

Polymerisation will not occur.

Special protection information

Ventilation: Local exhaust at processing equipment to keep particulate below 15mg/m³
(OSHA limit for particulates not otherwise regulated)

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OTHER INFORMATION

First aid measures (in case of)

Inhalation:	Not applicable.
Skin contact:	Do not use in case of a specific allergy. In case of permanent irritation, call for physician.
Contact with eyes:	In case of accident or accidental contact with the moving instrument call for physician.
Personal protection equipment:	
- Eyes	Safety glasses.
- Gloves	None under normal processing.
- Respirator	Not applicable.
Accidental dispersion:	May be swept up or mechanically collected.
Toxicology:	There is no toxicological data specific to this product in its moulded state.
Transportation:	The product should be transported in original containers to avoid damage or leakage. Keep containers dry.

Handling and Storage

There are no specific handling requirements, store in clean dry conditions at room temperature and away from light.

Disposal procedures

Aquatic toxicity:	Not applicable.
Spill or leak:	Sweep up to prevent slipping hazard.
Waste disposal:	Industrial recycling is recommended. Incinerate or landfill in compliance with National & local regulations.

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.

This TDS was prepared and is to be used only for the above product Ref(s).

The instructions for conditions of storage or methods of safe handling, use or disposal of the product must be followed, but maybe beyond our control. We do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the improper handling, storage, use or disposal of the product.

Articles as defined in OSHA Hazard Communication Standard, Section 1910.1200

These instruments are considered manufactured "articles" and, as such are exempt from Material 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.