

1: Identification of the device**1.1. Product identifier**

Diamond separating strips for the dentist

1.2. Relevant identified uses of the device and uses advised against

- Cleaning and shaping of the interproximal area in dentistry
- Not to be used on soft tissues
- To be used by trained personnel only

1.3. Details of the supplier of the safety data sheet

Hopf, Ringleb & Co. GmbH & Cie. , Gardeschützenweg 82, 12203 Berlin – Germany

Trade name: HORICO®

Phone: +49 30 830 003 – 0

E-Mail: horico@horico.de

2: Hazards identification**2.1. Classification of the device**

medical devices of risk class 1 (hand driven, without measurement function, non steril/according to European, FDA and Canadian regulations)

According to RKI directives regarding reprocessing of medical devices separating strips are semi-critical B Device needs to be disinfected or sterilized before first and before every further use according to reprocessing instructions provided by the manufacturer.

2.2. Identification and Symbols

CE-sign

2.3. Other hazards

Nickel can cause allergic reactions, occurrence if used as intended: very rare

3: Composition/information on components

Stainless steel strip galvanically coated with a nickel bonding holding diamond grid as abrasive

4: First aid measures**4.1. Description of first aid measures**

Intended use can cause small lesions on gingiva of the patient or hand of the user
Disinfection of the lesion and covering if applicable is recommended

4.2. Most important symptoms and effects, both acute and delayed

Light bleeding, inflammation of the lesion

4.3. Indication of any immediate medical attention and special treatment needed

non

5: Firefighting measures**5.1. Extinguishing media**

No restrictions

5.2. Special hazards arising from the device

Non

5.3. Advice for firefighters

Non

6: Accidental release measure

The device itself carries no hazards, but infectious tissues and material can be spread while working with the strip and afterwards.

6.1. Personal precautions, protective equipment and emergency procedures

Responsible: FH

Personal infection protection is recommended (surgical mask and gloves)

6.2. Environmental precautions

Chair and other surfaces of the practice need to be disinfected after each patient treatment

6.3. Methods and material for containment and cleaning up

Storage after use and before reprocessing according to infection control protocol of the practices

7: Handling and storage

7.1. Precautions for safe handling

Edges of the strip can be sharp – surgical gloves

7.2. Conditions for safe storage, including any incompatibilities

Before use and after reprocessing: Dry and clean storage

Shelf life is only limited by the durability of the packing

7.3. Specific end use(s)

Lifetime is only limited by wear out – it needs to be checked before each use

Signs of wear out: blank areas on the coated sides of the strip, performance of abrasion declines

8: Exposure controls/personal protection

Non

9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Stainless steel:

Physical state at 20°C and 101,3 kPa: solid

Melting point: about 1375°C

Boiling point: about 2750°C

Relative density: 7,9g/cm³ at 25°C

Surface tension: n.a.

Water solubility: n.a.

Burning point: n.a.

Inflammability: not inflammable

Explosion characteristics: not explosive

Self-ignition: no self-ignition

Oxidative characteristics: not oxidative

Stability in organic solvents: n.a.

Nickel layer (galvanically applied, solid):

Physical state at 20°C and 101,3 kPa: solid

Melting point: 1455°C

Boiling point: 2730°C

Relative density: 8,9g/cm³ at 25°C

Surface tension: n.a.

Water solubility: n.a.

Burning point: n.a.

Inflammability: not inflammable

Explosion characteristics: not explosive

Self-ignition: no self-ignition

Oxidative characteristics: not oxidative

Stability in organic solvents: n.a.

Diamond grit:

Physical state at 20°C and 101,3 kPa: solid

Melting point: above 600°C

Boiling point: 2730°C

Relative density: ca. 3,5g/cm³ at 25°C

Surface tension: n.a.
Water solubility: n.a.
Burning point: n.a.
Inflammability: not inflammable
Explosion characteristics: not explosive
Self-ignition: no self-ignition
Oxidative characteristics: not oxidative
Stability in organic solvents: n.a.

9.2. Other information

Non

10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Stable under normal conditions

10.4. Conditions to avoid

non

10.5. Incompatible materials

Strong acids and oxidants

10.6. Hazardous decomposition products

Nickeltetracarbonyl gas under deoxidizing atmosphere

11: Toxicological information

Oral: non toxic

Inhalation: n.a.

Dermal: n.a.

Eyes: mechanical irritation

Sensibilization:

Respiratory system: no information available

Skin: no information available – nickel can cause allergic reaction in case of longer expositions

12: Ecological information

12.1. Toxicity

Non

12.2. Persistence and degradability

n.a.

12.3. Bioaccumulative potential

Non, as nickel is solid

12.4. Mobility in soil

Non, as nickel is solid

12.5. Results of PBT and vPvB assessment

Not classified as PBT and vPvB

12.6. Other adverse effects

Non identified

13: Disposal considerations

13.1. Waste treatment methods after use

Disposal according to local and national regulations for potentially infectious material

13.2. Waste treatment methods before use

Disposal according to local and national regulations for recycling of metals

14: Transport information**14.1. UN number**

Non

14.2. UN proper shipping name

non

14.3. Transport hazard class(es)

Non

14.4. Packing group

Non

14.5. Environmental hazards

Non

14.6. Special precautions for user

Non

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

n.a.

15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the device
ISO 13485:2016; Directive 93/42/EEC; MDR of EU, USA and Canada

15.2. Chemical safety assessment

N.a.

16: Other information

non