

**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](mailto: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**

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/cm<sup>3</sup> 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/cm<sup>3</sup> 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/cm<sup>3</sup> 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