

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

Steel Strips - separating strips for the dentist

Ribbon saw - separating strips for the dentist

Prophylaxis strip – separating strip for the dentist and hygienist

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

- separating and guarding teeth and fillings in 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-sterile/according to European, US and Canadian regulations)

According to RKI directives regarding reprocessing of medical devices separating strips are hygienically 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**

Non identified

**3: Composition/information on components**

Stainless steel containing Nickel

**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

**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

Strips with bent edges or otherwise damaged areas and ripped strips need to be sorted out and disposed.

**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 – minimum 10 years if properly stored

**7.3. Specific end use(s)**

Steelstrips are used for separating teeth and protecting untreated teeth.

Prophylaxis strip with sharp edges around the perforation is used by hygienists to clean the interproximal area from stain and plaque.

**8: Exposure controls/personal protection**

Non

**9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Stainless steel: 1.4310

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.

The stainless steel contains Nickel in a concentration of < 38% by mass.

**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

Quality Management: ISO 13485:2016; Directive 93/42/EEC; MDR of EU, USA and Canada

Risk management: ISO14971:2015; ISO 10993-1:2009; DIN EN 62366:2008

Reprocessing: DIN EN ISO 17664:2004; ISO13402:2001; RKI-Rekommandations: Infektionsprävention in der Zahnheilkunde (2006), Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten (2012)

Labeling: ISO 21531:2009; EN 980; ISO 7711-3:1995

Materials: DIN 1544; DIN EN 1641; ISO 13402:2001; DIN 17440:1996

Measuring: ISO 6507-1:1982; ISO 6507-1:1983

15.2. Chemical safety assessment

N.a.

**16: Other information**

non