1: Identification of the device

1.1. Product identifier

Steelcarbo Strips - separating strips for the dentist with synthetic ruby as abrasive

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 componants

Stainless steel strip galvanically coated with a nickel bonding holding synthetic ruby 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

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 practies

7: Handling and storage

7.1. Precautions for safe handling
Edges of the strip can be sharp – surgical gloves
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
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)
Strips are used in the field of orthodontics for reduction of the interproximal area and shaping the interproximal contact points. In the field of dentistry they are manly used for shaping, smoothing and separating interproximal restoratives or cleaning.

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.

Synthetic ruby grit:

Physical state at 20°C and 101,3 kPa: solid
Melting point: 2072°C
Boiling point: 2970°C
Relative density: ca. 4,1g/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:
Repiratory 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