

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

GMDN code: 35702

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

- separating and guarding teeth and fillings in the interproximal area in dentistry

Intended use:

Dental separating strips are used for cleaning and separating of the interproximal area res. guarding fillings in the interproximal area in dentistry

They are intended for use by dentists and trained technicians.

Contraindications:

Separating strips shall not be used, if:

1. The instrument is not cleaned and disinfected/sterilized according to instructions for use before treatment.
2. The health status of the patient can be affected negatively by accompanying medication or stress cause by the treatment.
3. The mental health of the patient can be affected negatively by the noises or stimuli caused by the treatment. (e.g. states of fear)
4. The abrasion/dust caused by the use of the burs on restauration materials is allergenic or toxic and can be swallowed or inhaled by the patient or dentist.

1.3. Details of the supplier of the safety data sheet

Dr. Hopf GmbH & Co. KG , Bayernstr. 9, 30855 Langenhagen – Germany

Trade name: Sunshine® Diamonds

Phone: +49 30 830 003 – 0

E-Mail: info@sunshine-dental.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

Primary code: follows HIBC-Standard: beginning with licensed manufacturer code (HIBCC)

+ESUN<Item number><Packing index>/<Lot number>/<Manufacturing date>

If item is medical device it is listed in the UDI Databases of EUDAMED (EU) and GUIDID (FDA USA)

Symbols used on the label:

	manufacturing date
	address of manufacturer
	Consult instructions for use
	To be sterilized in the autoclave
	Medical device
	Approved quality management system, self-declared according to directive 93/42/EEC

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)

Steel strips 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/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.

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-Rekommandation: 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