

## Vliwaktiv® Ag

Activated charcoal rope with silver, sterile

REF 20700 – 20702

February 2019

### 1. Composition of the product

Vliwaktiv® Activated Charcoal Rope with Silver consists of:

Nonwoven cover: Polyester/polyethylene (PES fibres covered in PE)

Core: - activated charcoal cloth (activated charcoal fibres impregnated with silver salt; Borax)

This product data sheet covers the following items:

REF	Product description	Size
20700	Vliwaktiv® Activated Charcoal Rope with Silver	6,5 x 10 cm
20701	Vliwaktiv® Activated Charcoal Rope with Silver	10 x 10 cm
20702	Vliwaktiv® Activated Charcoal Rope with Silver	10 x 15 cm

### 2. Packaging, structure and composition

#### 2.1 Unit container

1 piece = 1 peel pouch consisting of cellulose and polyethylene

#### 2.2 Shelf container

10 pieces = 1 folding box (cellulose)

1 instructions for use (cellulose)

#### 2.3 Transit container

1 corrugated cardboard box (cellulose), contains:

REF	pieces	folding boxes
20700	300	30
20701	300	30
20702	340	34

### 3. **Manufacture**

Vliwaktiv® Activated Charcoal Rope with Silver is produced according to specification in hygienic conditions, packed as described in its relevant packaging specification. The product is sterilized by radiation in compliance with DIN EN ISO 11137.

### 4. **Description**

Vliwaktiv® Activated Charcoal Rope with Silver consists of a nonwoven cover and a core. The nonwoven cover is heat-sealed on all sides.

Vliwaktiv® Activated Charcoal Rope with Silver is available in three different sizes.

### 5. **Properties**

Vliwaktiv® Activated Charcoal Rope with Silver is an antimicrobial rope with odour-binding and bacteria-absorbing properties.

### 6. **Intended purpose** (see valid instructions for use)

Vliwaktiv® Activated Charcoal Rope with Silver is indicated for the treatment of critically colonized, infected and/or offensive smelling wounds as well as for wounds with an increased risk of infection. For the specific indication see instructions for use.

### 7. **Medical device classification**

Vliwaktiv® Activated Charcoal Rope with Silver are medical devices of class IIb according to rule 4.

(Council Directive 93/42/EEC concerning medical devices, Annex IX)

### 8. **Biological evaluation and biocompatibility** (DIN EN ISO 10993)

The starting materials used in the manufacture of Vliwaktiv® Activated Charcoal Rope with Silver are safe if the product is used appropriately.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

### 9. **Contraindications (note, see instructions for use)**

Some recent technical tests revealed the presence of the boron compound borax in the nonwoven material of activated charcoal used in our product Vliwaktiv® Ag.

Various boron compounds are classified as “toxic for reproduction” (CMR), category 1B, and are, thus, considered as SVHC (= substances of very high concern) according to the REACH regulation (Regulation (EG) No. 1907/2006). This applies for all product variants of Vliwaktiv® Ag.

Therefore the following contraindication has been added:

- Vliwaktiv® Ag should not be used in children less than 12 years old as the contained boron (in borax) may have the potential to impair fertility in the future.
- The use of Vliwaktiv® Ag in pregnant and lactating women should be carefully considered by the clinician in charge as a case-by-case decision.

In case of a concentration higher than 0,1 % (w/w) a labelling requirement is mandatory for these substances according to the Medical Device Regulation (Regulation (EU) 2017/745).

SVHC: **S**ubstances of **V**ery **H**igh **C**oncern (according to Regulation (EC) No. 1907/2006 (REACH))  
CMR: **C**arcinogenic, **M**utagenic, **R**eprotoxic  
Borax: Disodium Tetraborate Decahydrate, Na<sub>2</sub>B<sub>4</sub>O<sub>7</sub>\*10 H<sub>2</sub>O,  
CAS Nr. 1303-96-4

## 10. Stability

Stored appropriately Vliwaktiv® Activated Charcoal Rope with Silver has a shelf life of 5 years.

## 11. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.

Packaging materials must also be disposed of in compliance with applicable national requirements.

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signed by

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