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 Addition1
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 2020-02



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[Date]
 19/03/2020

Field Safety Notice (FSN) - SERVONA silver cannula (REF see enclosure)

Dear customer,

We would like to inform you today about Field Safety Notice regarding Servona silver cannulas. Please find enclosed with this letter an updated instruction manual for your Servona silver cannula. Risks identified as part of our risk management process have resulted in changes to the cleaning procedure described in the instruction manual.

The changes to the instruction manual are a preventive measure. To date, Servona has not received information about any health consequences having arisen for a patient.

The following silver cannulas are affected by the amendments to the instruction manual:

Article number	Description
32851 - 32865	SERVONA silver cannula (3 parts)
32911 - 32925	SERVONA silver cannula (3 parts, extra long)
32836 - 32850	SERVONA silver cannula (standard)
32896 - 32910	SERVONA silver cannula (standard, extra long)
32866 - 32880	Servona silver speech cannula with standard connector
32926 - 32940	Servona silver speech cannula with standard connector, extra long
32881 - 32895	Servona silver speech cannula with O2 connector
32941 - 32955	SERVONA silver speech cannula (standard)
32956 - 32970	SERVONA silver cannula (standard, extra long)

Please read the instruction manual carefully before continuing to use the Servona silver cannula and pay particular attention to the following sections from the instruction manual (excerpts from the instruction manual):

Manager
 Commercial
 register

Jörg Riemann
 Siegburg Local Court HRB 9940
 Institution Code No.: 33 053 0944
 VAT ID No.: DE 122950345, WEEE-Reg-No.
 DE21209435

Bank account
 Commerzbank AG Köln

IBAN: DE40 3704 0044 0500 2167 00
 SWIFT: COBADEFF370

Bank account
 Deutsche Bank AG Köln

IBAN: DE38 3707 0060 0244 0030 00
 SWIFT: DEUTDEKXXX

Excerpts from the instruction manual:

Safety warnings:

...

Warning



Risk of inflammation/ irritation: Residues of cleaning agents or residual impurities on the tracheal cannula resulting from incomplete or improper cleaning can cause irritation or inflammation of the tracheostoma or trachea.

- Always clean your tracheal cannula exactly as specified in this instruction manual!
- Always rinse your tracheal cannula thoroughly after cleaning to ensure that no cleaning agent residues remain!

Please note!

- Do not perform any other cleaning operations than those described in Chapter 12.4! Other, e.g. machine cleaning processes, could damage the tracheal cannula.

Required aids and accessories (for cleaning)

- Correctly sized cannula cleaning brush (e.g. SERVOX cannula cleaning brush). The cleaning brush should be flexible, with soft bristles and a rounded tip, in order to prevent damage to the cannula.
- Suitable cleaning tub with a sieve insert (e.g. SERVOX cleaning tub with sieve insert)
- Commercially available pH-neutral fragrance-free washing lotion (e.g. Balea Waschlotion pH 5.5 skin-neutral soap-free)
- Access to warm clean running water

Cleaning instructions (12.4)

1. To remove larger impurities, carefully flush the tracheal cannula and the speech valve with lukewarm running water. Remove firmly attached secretion with a suitable cleaning brush. Prior to use, the cannula cleaning brush should be bent into the same shape as the cannula.

Tracheal cannula: Always insert the cleaning brush from the tip of the cannula and carefully move up and down the inside with slight pressure for at least 30 seconds. Prior to removing the brush, clean the brush head under running water. Then brush the outside of the cannula for a further 30 seconds. Avoid excessive pressure and do not use any other aids such as scrapers, knives or fingernails to avoid damages.

Speech valve: If cleaning the speech valve with the cleaning brush is required, the brush must not be pushed through the valve opening in order not to damage the valve. After the removal of the major impurities, clean the cleaning brush thoroughly under running water.

Please fully complete the response letter, and sign and return it to us.

Please ensure that all users of the above products and other persons to be informed within your organisation are aware of this Field Safety Notice. If you have sold any products affected by this FSN to third parties, please forward a copy of this information or inform the contact listed below.

Please keep this information at least until the measures have been completed.

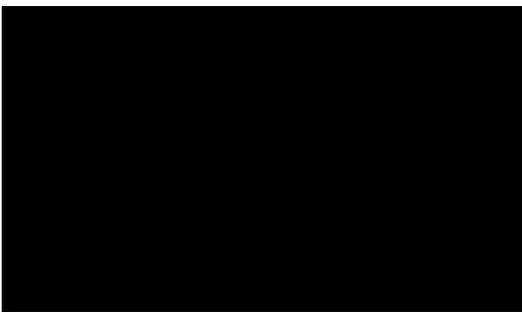
The Federal Institute for Drugs and Medical Devices has received a copy of this "Field Safety Notice".

We would like to thank you for your understanding and for your support in the implementation of the corrective measures. We would also like to apologise for any inconvenience caused by these measures.

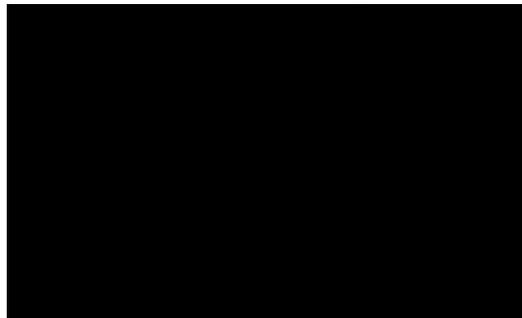
With kind regards

Servona GmbH

i. A.



i. A.



Enclosures

Response letter
Instruction manual

