Instruction manual for

Skin-Elast-Hook

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1. **Why use an "instruction manual"?**

The European Medical Device Directive and the national legislation on marketing, setting up and prosecuting medical products require the manufacturer to provide "information about the medical product". The manufacturer of the here described medical product is Fa. Customized Medical Device (further referred to as CMD).
An instruction directly printed on the product is impossible due to shortage of space. To add a so called instruction leaflet to every delivery is not advised due to applicable and ecological reasons.
CMD therefore uses labels on each medical product which refer to this instruction manual.
A medical product adviser can help if additional instruction is needed.

Your signature on the training form of this **instruction manual** confirms that you have received a comprehensive and broad instruction of the item and that all your questions have been answered.

CMD **1.1 Specific function of medical products**

All medical products marketed by CMD are meant for single-use on a patient and are to be disposed by the customer right on-site.
The Skin-Elast-Hook galea hook is used for surgeries for example head surgeries, surgeries on ear, nose and throat, on jaws, general surgeries or rather comparable ones.
The period of usage can take several hours depending on the kind of intervention and must not exceed 24 hours.

CMD 1.2 Introduction

CMD was certified by a nominated authority (TÜV/Technical Control Board-Austria) concerning EN ISO 13485 and also RL 93/42/EWG and is controlled at regular intervals. You will find name and full address of CMD in the appendix of this manual.
The used products are single-use products as defined by Medical Device Directive (MPG). Products are not to be re-used and re-use is generally and strictly excluded by the manufacturer since further thermic strain of the tension springs

will eventually take place due to additional rework. Therefore, modifications of the product characteristics cannot be prevented. Hence, a re-use is not allowed.

2. System

2.1 Types of packaging for sterile items

Sterile items are provided in the following kinds of packaging:

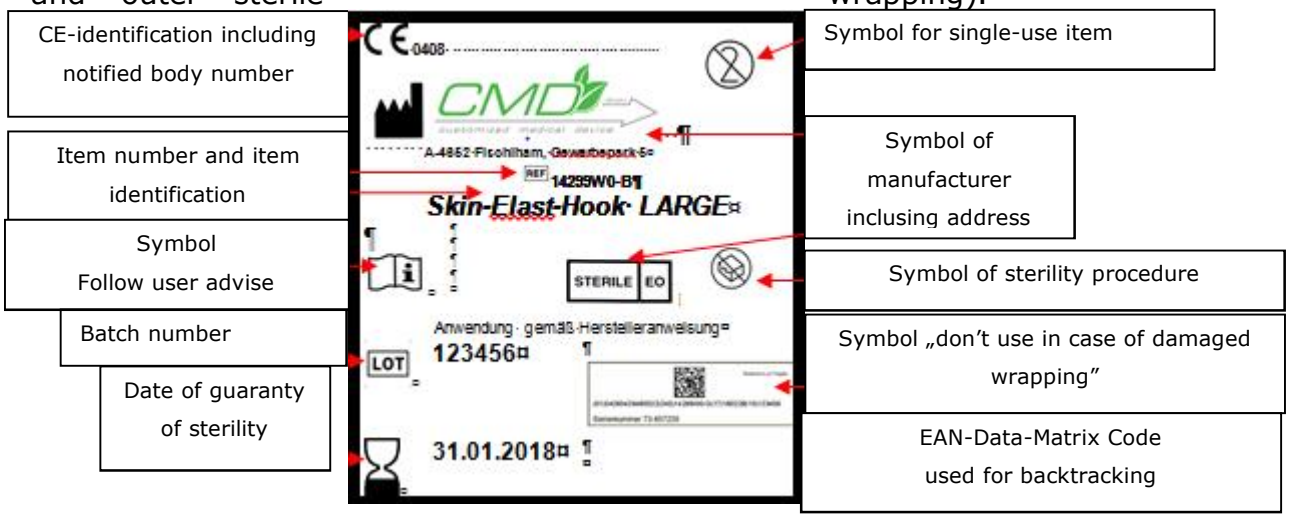
- wrapping in double Blister Tyvek wrapper

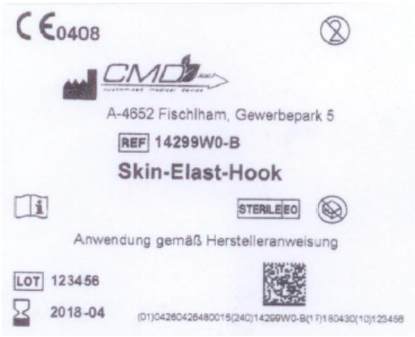
2.2 Identification marks of sterile items

Sterile items are identified on the inner and outer sterile wrapping as described. It will be printed in different sizes on the inner and outer wrapping and contains the following contents displayed.

The identification printed onto the label of this instruction by the manufacturer is shown to the user by noting "Usage according to instructions by the manufacturer". Further on, required information for proper usage are given (see examples).

Patient labels have been developed especially for the patient documentation (see 2.3). It is attached loosely to the outer sterile wrapping (in between the inner and outer sterile wrapping).





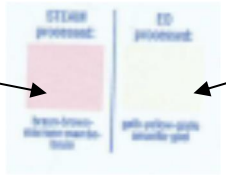
Inner sterile identification outer sterile identification patient label

Example: wrapping in Blister Tyvek wrapper

The indicator changes color due to sterilization depending on the procedure. The left field changes color due to sterilization with steam BROWN or rather the right field due to sterilization with ethylene oxide (EO) YELLOW (see picture).

2.3 Label explanation

Steam sterilization BROWN change of color



EO- sterilization YELLOW change of color

CE 0408

CE-identification with the number of the nominated place: the CE-identification acknowledges the conformity of the basic requirements or rather according to the 93/42/EWG guideline. Due to the following 4-digit number the "place" which performed the conformity movement procedure nominated by MPZ® is visible (for example 0408 = TÜV-/Technical Control Board Austria, 0123 = TÜV-/Technical Control Board Product Service, 0124 = DEKRA, 0481 = ECM, and so on).

Usable until

The product must not be used after this date and is to be disposed.

Symbol for **sterilization with ethylene oxide**

Symbol for **"pay attention to instruction manual"**

This is a reference to the present manufacturer advice.

Symbol of the **manufacturer**

This serves as an advice that CMD GmbH appears as manufacturer.

Symbol for "not supposed to be re-used".

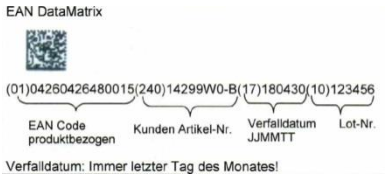
Serves as an advice that this medical product is intended for single-use only since further thermic strain of the tension springs will eventually take place due to additional rework. Therefore, modifications of the product characteristics cannot be prevented. Hence, a re-use is not allowed.

Symbol for "don't use in case of damaged wrapping".

Serves as an indicator that this medical product only guarantees the specified sterility if the wrapping is faultless. In case of damaged wrapping the medical product must not be used and has to be disposed.

Patient label for maintenance documentation

This label is intended for the maintenance documentation and serves the documentation of used items. When opening the outer sterile wrapping this label is supposed to be taken out and the corresponding patient documentation is to be added. This label describes the correlation through the EAN DataMatrix-Code to the batches of rework.



REF-Number

This is the item number of the single sterile item.

There are 2 different sizes and varieties for the Skin Elast Hook and therefore 4 different item numbers:

14299W0-B, 14299W0-G (Skin-Elast-Hook-LARGE),

15097W0-B, 15097W0-G (Skin-Elast-Hook-SMALL).

The item numbers 14299W0-B, 14299W0-G (Skin-Elast-Hook-LARGE) were specially developed for application on children and therfore the hook has a total length of approximately 2mm smaller and the distance between the hooks was chosen to be smaller. The tension springs are used with the same length and format as described further down.

(Skin-Elast-Hook-LARGE), (Skin-Elast-Hook-SMALL

14299WO-B **14299WO-G** **15097WO-B** **15097WO-G**

Here, only the elasticity of the tension spring varies. This is indicated by using different colors.

Item number

14299WO-B Blue tension spring with more stiffness and therefore also with less possibility for extension.

15097WO-B The blue tension spring shows less possibility for extension and is supposed to be used at fields of operation with small ranges up to approximately 70cm.

14299WO-B **15097WO-B**

Article number

14299WO-G green tension spring with less stiffness and therefore more elasticity.

15097WO-G The green tension spring shows more elasticity and is supposed to be used at fields of operation with greater ranges up to approximately 90 cm.

LOT

Lot-number

This is the labelling for the batch number which allows backtracking the rework of the batch documentation.

2.4 Storage of sterilely delivered medical products

Storage of sterile medical products has to be carried out according to the valid storage conditions (DIN 58953-7 or rather DIN 58953-8). Due to 8.1 (storage), this norm requires storage and stockpiling to be carried out in dustless and dry rooms which are not open to general traffic. Storage in cabinets is not advised.

The rooms need to free of vermin. The inner sides (walls, floors and ceilings) need to be flat and without cracks, easy to clean and to disinfect.

Stockpiling needs to be adapted to the usage due to hygienic and economic reasons. In case of storage in cabinets a ground clearance of at least 30 cm is to be maintained.

Abiding the storage conditions (DIN 58953-7 or rather 58953-8) the company guarantees the sterility of the medical product for up to 3 years after the applied sterilization in case of undamaged sterile wrapping.

Prior to usage, the date of the guaranty of sterility has to be checked and must not be exceeded.

2.5 Opening of sterile medical products and removal of sterile items

Prior to opening the sterile wrapping the following needs to be observed (also see DIN 58953-7):

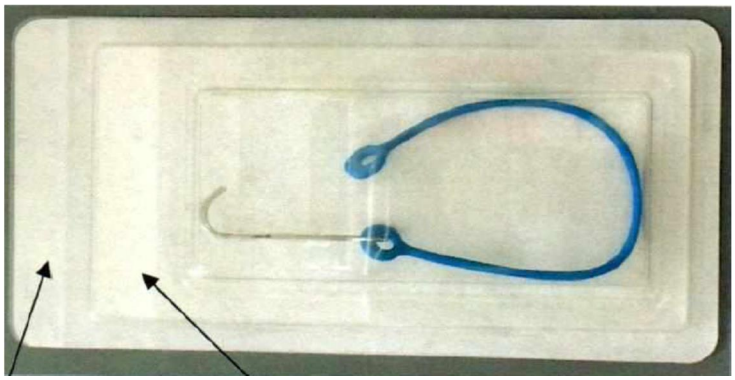
- Prior to opening the protective packaging, it is supposed to be freed from possible particle accumulation.
- The protective packaging is supposed to be removed just shortly before actually using the sterile items.
- The protective and sterile packaging of the items needs to be checked for

visible damages.

The sterile items can only be used in case of undamaged protective and sterile packaging.

The sterility of the medical product starts on the inside of the outer wrapping.

The sterile items can only be opened and remove by trained staff.



Opening strap	opening strap
Outer sterile wrapping	inner sterile wrapping

3. Application

Your medical product adviser will give you an on-site instruction including a product presentation concerning appropriate and proper use. During the whole period of business relations the adviser will be your contact person for questions concerning application and use. In general, medical products are only to be used according to their appropriate and proper purpose.

Application can only be carried out by specialized personnel. Specialization of staff members is carried out by the supervisor of the operation room. The medical product adviser can support upon request.

During usage, it is important to maintain constant and even distribution of elasticity. This can be achieved through usage at a preferably right-angle to the wound. The flexible shaft supports that.

Overexpansion of the tension spring is to be prevented.

The tension spring must not be strained over edges.

To fix the tension spring the usage of "Backhaus" fixture as advised.

Depending on the surgery and the size of the wound, the usage of more than one hook is advised.

3.1 Objection

Objected items can be returned to under specification of reclamation reason.

For an exact error analysis it is of utmost importance to state the serial number of the patient label.

4. Basic instructions for item usage

4.1 Guaranty of sterility

The guaranty of sterility of the sterilized surgical items by is maintained for 3 years in case of appropriate use and proper storage. Prior to usage the date of the guaranty of sterility is to be checked and must not be exceeded.

In case of usage of expired surgical items the Fa. does not take liabilities or responsibilities. Expired items are to be disposed accordingly (see disposal).

5. User acknowledgement

Your signature on the attached proof of training confirms that the instruction manual has been presented to the supervisor of the operation room by the responsible medical product adviser and was explained in detail. All questions have been answered accordingly.

It has been pointed out to the trained supervisor of the operation room that other, further or new members of the hospital must be trained and instructed by the trained supervisor prior to usage of medical devices.

6. Contact persons

	Customized Medical Device GmbH Gewerbepark 5 A-4652 Fischlham Tel. Nr.: 07245-25570 Fax: DW 20 Email: office@cmd-medical.at	
Head of the company	Mr. Christian Hefner	07245/25570
Medical product adviser/ Official in charge of objection/ product development	Mr. DGKP Walter Höckner	07245/25570
Quality management	Mr. Robert Köttner	07245/25570
Security official for medical products	Mr. Robert Köttner	07245/25570

7. Appendix

List of participants for instructions on how to use this manual