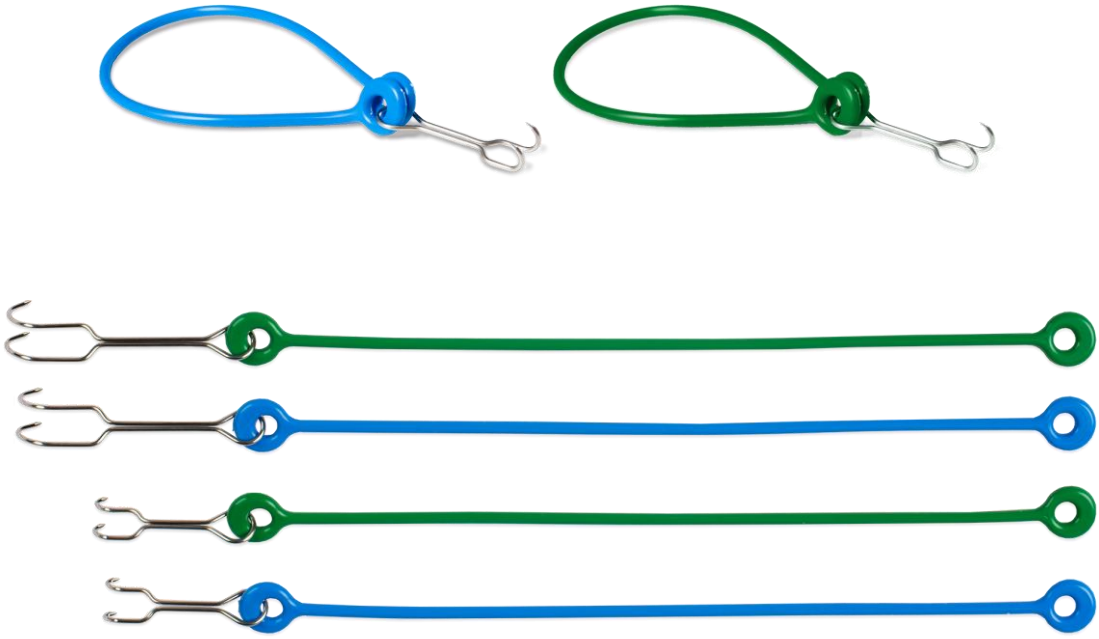
Instructions for Use

SKIN-ELAST-HOOK

A-4652 Fischlham, Gewerbepark 5



Medical devices manufactured in Austria!

These instructions were put together with great care. If you should still find details here, which do not agree with how the system is handled, we would appreciate it if you let us know so that we can correct the discrepancies as quickly as possible.

Should there be a serious incident or undesirable side effects during handling and use of the product which are not specified in these instructions for use, please report these to us with a detailed description of the incident or side effects. Please use the contact details below for this purpose.

The specifications and figures in this user manual are subject to change due to optical or further technical developments.

Information about the product and the manufacturer

Skin-Elast-Hook

A product by:

CMD GmbH
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Version of these instructions for use

Version 05 - March 2025

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1 Product Description

The medical device is a retractor with a silicone spring, which is known as a Skin-Elast-Hook and is marketed in 2 different sizes of retractors and silicone springs and therefore 4 different article numbers.

1.1 Product Variants

Article name	Description	Article number
Skin-Elast-Hook-LARGE (blue)	Retractor with large hook and blue silicone spring with higher hardness and therefore lower stretch behaviour.	14299WO-B
Skin-Elast-Hook-LARGE (green)	Retractor with large hook and green silicone spring with a lower hardness and therefore higher elongation behaviour.	14299WO-G
Skin-Elast-Hook-SMALL (blue)	Retractor with small hook and blue silicone spring with a higher hardness and therefore lower stretching behaviour.	15097WO-B
Skin-Elast-Hook-SMALL (green)	Retractor with small hook and green silicone spring with a lower hardness and therefore higher elongation behaviour.	15097WO-G

Item numbers 15097W0-B, 15097W0-G (Skin-Elast-Hook-SMALL) have been specially developed for use on children. They are approx. 20 mm shorter in overall length and the distance between the hooks is narrower. The silicone springs are used in the same length and design as described below.

The silicone springs are differentiated according to the tension force. This is indicated by the different colours.

The blue silicone spring has a lower elongation behaviour and can be used for applications with smaller spans of up to approx. 70 cm.

The green silicone spring has a higher elongation behaviour and should be used for applications with larger spans of up to approx. 90 cm.

1.2 Intended Purpose

The purpose of the retractors is to spread the surgical wound and hold tissue away to give the surgeon better access to the surgical site.

1.3 Intended Patient Population

Patients with a need for wound spreading. There are no restrictions in terms of age, gender, size, etc.

1.4 Medical Indications

The indications for the use of Skin-Elast-Hooks are surgical procedures that require:

- The keeping aside of tissue (skin, connective tissue, muscles) and/or
- The spreading of the surgical wound

1.4.1 Contraindications

The retractors must not be used for the following purposes/in the following situations:

- Use of hooks in tumour tissue
- For spreading wounds caused by injuries
- For securing other medical devices
- For large-area burns to the skin
- For degenerative diseases that impair the elasticity of the skin

1.5 Intended User

The users are surgical personnel.

The system is used exclusively by trained specialised personnel. Other employees are trained by the theatre management. If required, the medical device consultant can provide support.

1.6 Intended Use

Intended place of operation

The Skin-Elast-Hook is to be used in the operating theatre.

Intended use environment

Ambient conditions in the operating theatre.

Intended body site of application

Entire body on skin, connective tissue and muscles. No contact with the CNS is intended.

Intended duration and intended frequency of use

The duration of the procedure or period of use is usually more than 60 minutes, but can last several hours depending on the procedure and is in any case less than 24 hours. Continuous contact is not intended. The application is one-off.

Intended location of contact and intended type of contact

The hook comes into contact with the surgical wound - direct contact with injured skin.

There is no contact with the CNS.

The silicone spring does not come into contact with the wound.

Invasiveness

Surgically invasive medical device.

Intended duration of contact

Short-term contact according to DIN EN ISO 10993-1.

The intended contact time of the retractor is less than 24 hours.

Cleaning, disinfection and sterilisation

The retractor is supplied sterile. The retractor is intended for single use and therefore does not require cleaning, disinfection or sterilisation by the user.

1.7 Precautions and safety instructions

Precautions

Before opening the sterile packaging, the following points must be observed:

- Before opening the protective packaging, remove any possible particle deposits.

- The protective packaging should only be removed shortly before the sterile supplies are used.
- The protective and sterile storage packaging of the items must be checked for visible defects.
- The sterile supplies may only be used if the protective and sterile storage packaging is undamaged.
- The sterility of the medical device begins on the inside of the outer packaging.
- The sterile supplies should only be opened and removed by trained personnel.

Please note the following during use:

- During application, care must be taken to distribute the silicone force evenly. This is achieved by inserting the spring as perpendicular to the wound as possible.
- Avoid overstretching the silicone spring.
- The silicone spring must not be tensioned over sharp edges.
- The use of Backhaus clamps is recommended for fastening the silicone spring.
- Depending on the procedure and the size of the wound, the use of several retractors is recommended.
- The used retractors must be disposed of with the other medical waste produced by the user.

Safety Instructions

Do not use the Skin-Elast-Hook product in tumour tissue!

Do not use the Skin-Elast-Hook product if the product packaging is damaged!

Do not use the Skin-Elast-Hook product if the expiry date has passed!

1.8 Clinical claims

Retractors are used to keep the surgical field open and to keep tissue aside. The services that serve to fulfil the purpose are only indirectly clinical or purely technical. The retractors have no direct clinical benefit for patients and therefore no direct clinical benefit according to the definition of the MDR.

Indirect clinical performance

- The retractors keep the surgical field open
- The retractors enable retraction while keeping the surgical field easily accessible
- The retractors minimise the risk of contamination of the sterile field

Non-clinical claims

- The hooks have a specially milled conical tip
- The retractors offer the possibility of flexible and freely selectable fixation
- The silicone springs can be loaded with a tensile force of up to 30N (green) or 40N (blue)

Sterility claims

The retractor is sterile packed.

Indirect patient-benefits

Reduction of the risk of cross-contamination through single use.

1.9 Functional Description

1.9.1 Description of Functional Units

The Skin-Elast-Hook consists of a hook and a silicone spring.

Hook

The hook is made of stainless steel and has rounded, milled prongs and an open shaft. After the skin incision and preparation of the tissue, the hook of the Skin-Elast-Hook can be used in the wound area.

CMD offers 2 different sizes of hooks.

Silicone spring

The silicone spring is made of silicone, which makes it stretchable. After fixing the retractor, the silicone spring can be attached freely in the direction of silicone to the desired length. The silicone spring can be attached to the operating theatre cover or to special brackets in the sterile operating theatre area using a Backhaus clamp.

Intraoperative loosening and fixing are possible at any time. The length of the silicone spring is minimised by double looping.

CMD offers 2 different hardnesses of silicone springs (green: 40 Shore, blue: 60 Shore).

1.9.2 Description of the functionality

The retractors keep the surgical field open

Retractor with hook, which is placed in the tissue and a silicone spring, which applies tensile force to the hook and thus pulls the tissue outwards (towards the fixation point of the silicone spring)

The retractors enable retraction while keeping the surgical field easily accessible

Retraction is made possible by tensioning springs that run on the patient and do not protrude upwards and out of the operating field like frame systems. The retractors are attached to the operating table or the drape; no assistant is required to obstruct access to the operating field.

The retractors minimise the risk of breaching the sterile barrier

The retractors are supplied sterile and are intended for single use. This avoids reprocessing and the possibility of cross-contamination from improperly or incompletely reprocessed retractors.

The retractors feature a specially milled conical tip

Development has worked out a special milling of the hook tip, which results in a conical shape.

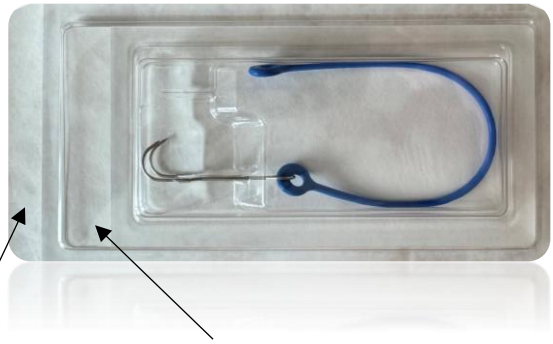
1.10 Packaging

Sterile articles are provided in two blister Tyvek packs.

1.10.1 Opening the sterile medical devices and removing the sterile supplies

Before opening the sterile packaging, the following points must be observed:

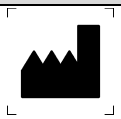
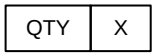
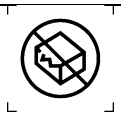
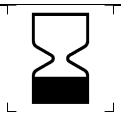
- Before opening the protective packaging, remove any possible particle deposits.
- The protective packaging should only be removed shortly before the sterile supplies are used.
- The protective and sterile storage packaging of the items must be checked for visible defects.
- The sterile supplies may only be used if the protective and sterile storage packaging is undamaged.
- The sterility of the medical device begins on the inside of the outer packaging.
- The sterile supplies should only be opened and removed by trained personnel.

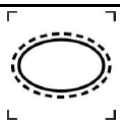
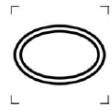
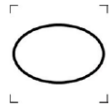


Opening flap
Outer sterile packaging

Opening flap
Inner sterile packaging

1.11 Labelling

Symbol	Meaning
	Manufacturer's name and address Supplementary see EN ISO 15223-1
	Product name and model, article number if applicable Supplementary see EN ISO 15223-1
	Quantity X of products contained in the packaging
	Date of manufacture Supplementary see EN ISO 15223-1
	CE-Symbol (for Class II/III devices, the four-digit identification number of the notified body involved)
	Batch designation Supplementary see EN ISO 15223-1
	Unique product identification Supplementary see EN ISO 15223-1
	Labelling of an object as a medical device Supplementary see EN ISO 15223-1
	Temperature range (obere Temperatur rechts oben, untere Temperatur links unten) Supplementary see EN ISO 15223-1
	Please consult the accompanying documents. Supplementary see EN ISO 15223-1
	Do not use if the packaging is damaged. Supplementary see EN ISO 15223-1
	Sterilised with ethylene oxide Supplementary see EN ISO 15223-1
	Usable Until Supplementary see EN ISO 15223-1

Symbol	Meaning
	Do not reuse Labelling for single-use products Supplementary see EN ISO 15223-1
	Single sterile barrier system with outer protective packaging Supplementary see EN ISO 15223-1
	Double sterile barrier system Supplementary see EN ISO 15223-1
	Single sterile barrier system Supplementary see EN ISO 15223-1
	Contains no natural rubber latex
	Safety Instruction (Warning notices have their origin in the risk assessment. They are required to draw the user's attention to residual risks or sources of danger)
CH-REP	Swiss Representative Authorized Representative in Switzerland Supplementary see EN ISO 20417

2 Safety Instructions

Read these instructions for use carefully. They are part of the device and must be available at all times. Do only use the device for the intended purpose described in this document (see chapter 1.2).

For your own safety as well as for the safety of your patients and according to the requirements of the Medical Device Regulation, please observe the following:

WARNING: Important safety or performance information or immediate response from operator required.

CAUTION: Other important information with or without the need of operator response.

2.1 General Remarks

	Follow the instructions for opening the sterile packaging
	The used retractors must be disposed of with the other medical waste produced by the user.

Table 3.1: General Remarks

2.2 Operation of the Device

	During application, care must be taken to ensure that the silicone force is evenly distributed. This is achieved by inserting it as perpendicular to the wound as possible. This is additionally supported by the flexible shaft.
	Avoid overstretching the silicone spring.
	The silicone spring must not be tensioned over sharp edges.

Table 3.2: Operation of the Device

2.3 Side Effects and Contraindications

	Do not insert the hooks into tumour tissue Do not insert the hooks in the case of extensive skin burns Do not insert the hooks in degenerative diseases that impair the elasticity of the skin
	Do not use the retractors to spread wounds caused by injuries
	Do not attach any other medical devices with the retractors

Table 3.3: Side Effects and Contra Indications

3 Operation

Read these instructions for use carefully. They are part of the product and must be available at all times. Only use the product for the purpose described in these instructions for use (see chapter 1.2).

3.1 Application of the Skin-Elast-Hooks

As part of the product presentation in your company, the medical device consultant will instruct you in the appropriate handling of the product. Throughout the entire business relationship, he or she will be your contact person for application questions. As a general rule, the medical devices may only be used for their intended purpose.

They may only be used by trained specialist personnel. Other employees are trained by the theatre management. If necessary, the medical device consultant can provide support.

- During application, care must be taken to distribute the tension force evenly. This is achieved by inserting it as perpendicular to the wound as possible. This is additionally supported by the flexible shaft.
- Overstretching of the silicone spring must be avoided.
- The silicone spring must not be tensioned over sharp edges.
- The use of Backhaus clamps is recommended for fastening the silicone spring.
- Depending on the procedure and the size of the wound, the use of several retractors is recommended.
- The used retractors must be disposed of with the other medical waste produced by the user.

The sterility guarantee of the surgical items sterilised in the steriliser is **29 months** after sterilisation if handled and stored correctly. Before use, check that the date of the sterility guarantee has not expired.

The company accepts no liability for the use of expired surgical items. Expired items must be disposed of accordingly (see Disposal).

3.2 Patient Documentation

A separate patient label has been developed for patient documentation.

When using a Skin-Elast-Hook, the corresponding patient label must be affixed to the patient file.

3.3 Reprocessing

The Skin-Elast-Hook is a disposable product and must not be reprocessed!

As any additional reprocessing also results in further thermal stress on the silicone springs, changes to the product properties cannot be ruled out and therefore reprocessing is not permitted.

4 Storage

Sterile medical devices must be stored in accordance with the applicable storage conditions. Point 8.1 (Storage) of the standard stipulates that sterile supplies must be stored and stockpiled in dust-free and dry rooms that are not accessible to the general public. Storage in cabinets is recommended.

The rooms must be free of vermin. The interior surfaces (walls, floors and ceilings) should be smooth and free of cracks, easy to clean and disinfect.

For reasons of hygiene and economy, storage should be adapted to requirements. For shelf storage, a floor clearance of at least 30 cm must be maintained.

Taking into account the storage conditions, the company guarantees the sterility of the medical devices for up to **29 months** after sterilisation if the sterile packaging is undamaged.

5 Disposal

The used retractors must be disposed of with the other medical waste produced by the user.

6 Reclamation

Rejected articles must be returned to the manufacturer, stating the reason for the complaint and notifying the manufacturer in advance. Attention! Products will only be accepted by the manufacturer if they have been cleaned and decontaminated by the sender in advance. All serious incidents occurring in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user is established.

It is very important that the serial number of the patient label is quoted in order to analyse the fault accurately.

7 User Confirmation

By signing the enclosed training certificate, you confirm that the instructions for use have been presented and explained to the relevant theatre management by our responsible medical device consultant. All questions were answered satisfactorily.

The instructed theatre manager has been made aware that further, other or new employees of the hospital must first be trained in the correct use of the MP products by the now instructed theatre manager before using the MP products.

8 Technical Data

8.1 Technical Parameters

Feature	Value
Product class according to Regulation EU 2017/745 (MDR)	Class IIa
Notified Body	ECM Srl – NB number 1282
Material hooks	Stainless steel 1.4301
Material spring	Silicone KEG-2000-60A/B bzw. KEG-2000-40A/B Silicone KEG-2003-60A/B bzw. KEG-2003-40A/B
Temperature range Transport	-20°C to +55°C
Temperature range Storage	+5°C to +30°C
Variants	14299WO-B, 14299WO-G 15097WO-B, 15097WO-G
Shelf life	29 months
Product life time	Single Use product

9 Appendices to the instructions for use

Enrolment certificate

10 Declaration of Conformity

The valid declaration of conformity can be found on the homepage www.cmd-medical.at.