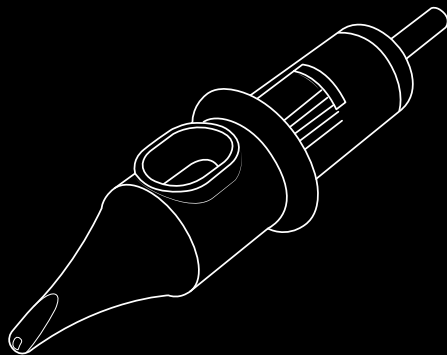


CHEYENNE[®]

CARTRIDGES



Gebrauchsanweisung
Instruction for use
Gebruiksaanwijzing
Manuel d'utilisation
Istruzioni per l'uso
Instrucciones de uso

Manual de instruções
Οδηγίες
Opskrift
Bruksanvisning
Ohjeet
Instrukcja obsługi

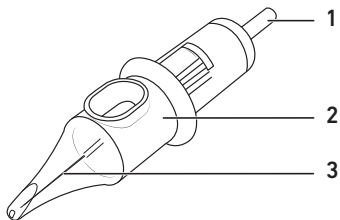
Instrukce
Navodila nt pl za uporabo
Utasítás
Инструкция
使用说明书

Translation of the original instructions for use. The original instructions for use were written in German.

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1 Product Overview



1

Shaft

2

Module body

3

Needle

2 About this Operating Manual



This operating manual applies to the needle cartridge. It contains important information about how to operate and maintain the needle cartridges safely and as intended.

This operating manual does not contain all of the information needed for safe operation of tattoo machines and their accessories. Therefore, observe the following additional documents:

- Operating manual for the tattoo machine and/or the power unit and, if applicable, and the foot switch
- Information about tattoo inks
- Safety data sheets about disinfectants and cleaning agents
- Health and safety information and statutory provisions relating to tattooing

3 Depiction of warnings

Warning notices draw attention to the risk of personal injury and damage to materials and are structured as follows:

 SIGNAL WORD	
Type of hazard	
Consequences	
▶ Remedy	
Element	Meaning
	Indicates a risk of injury
Signal word	Specifies the severity of the hazard (see table below)
Type of hazard	Gives the type and source of the hazard
Consequences	Describes potential consequences of non-compliance
Remedy	Indicates how to avoid a hazard
Signal word	Meaning
Hazard	Indicates a hazard that will definitely lead to death or to serious injury if the hazard is not avoided









Signal word	Meaning
Warning	Indicates a hazard that may lead to death or to serious injury if the hazard is not avoided
Caution	Indicates a hazard that can lead to minor to relatively serious injury if the hazard is not avoided
Attention	Indicates potential risks to the environment, property or equipment if this hazard is not avoided











Symbols used in this operating manual

Symbol	Meaning
▶	Call for action
•	List point
-	List sub-point

4 Symbols on the product

The symbols described below can be found in this operating manual, on the device, its accessories or packaging:

Symbol	Meaning
	Refer to operating manual!
	The product satisfies the requirements of directive 2006/42/EC (Machinery Directive).
	Attention!
	Warning of cutting or puncture wounds
	Manufacturer
	Date of manufacture
	Catalog number, order number
	Lot code

	Sterilized with ethylene oxide
	Use-by date
	Temperature limit
	Humidity limit
	Air pressure limitation
	Store in a dry place
	Cannot be used if packaging is damaged
	Do not reuse
	Do not re-sterilize
	The product satisfies the applicable requirements stipulated in legal regulations of the United Kingdom.

5 Important safety information

5.1 General Safety Information

- ▶ Carefully read this entire operating manual.
- ▶ Keep the operating manual in a readily accessible location for everyone who uses, stores, or transports the needle cartridges.
- ▶ Follow the safety regulations applicable to tattooing in your country. Keep your workstation in a hygienic, clean condition and provide sufficient lighting.
- ▶ Only use original needle cartridges.
- ▶ Never modify the needle cartridges or their accessories.
- ▶ Maintain the operating, transport and warehouse conditions that are stipulated in this operating manual (see chapter 9 on page 26).

5.2 Important hygiene and safety regulations

Please observe the following instructions to prevent contamination or infectious diseases from being transmitted to the client or user during treatment:

- ▶ During the tattooing process, wear disposable nitrile or latex gloves and disinfect them before use. When selecting an appropriate disinfectant, take note of the applicable regulations in your country.
- ▶ Before treatment, clean the affected areas of the client's skin with a mild cleanser and disinfectant. When selecting an appropriate disinfectant, take note of the applicable regulations in your country.
- ▶ Only use new, sterile-packaged needle cartridges for each client for each new application. Before each usage, ensure that the packaging is undamaged and that the expiration date has not passed. Take note of the batch number (lot number) of the needle cartridges used in the corresponding client file to be able to inform the manufacturer if any problems occur.
- ▶ Needle cartridges are sterile, disposable products (consumables) and must always only be used once!
- ▶ Dispose of used or defective needle cartridges as well as such needle cartridges with packaging that has been damaged, in a puncture-proof container (sharps container) in accordance with the regulations that apply in your country.

- ▶ Prevent needle cartridges from coming into contact with contaminated objects, e.g. clothing. Contaminated needle cartridges must not be used, but must instead be disposed of immediately. Comply with the regulations that apply in your country.

Injuries caused by contaminated needles or needle module may transmit diseases:

- ▶ Seek medical attention immediately if you experience a puncture wound from a contaminated needle!

5.3 Purpose

The purpose is the minimally invasive injection of sterile or aseptic pigment color of mineral or organic origin into the dermis by means of micropigmentation (tattooing).

The skin does not bear any open wounds given the minimally invasive puncturing of the epidermis (top layer of skin) and dermis (middle layer of skin). Therefore, the skin needs only a very short regeneration phase during which the epithelial function is quickly restored.

Application area

Body tattooing

5.4 Contraindications and side effects

Should there be even the slightest doubt that the safety of the client to be treated cannot be guaranteed, for example due to accompanying illnesses, refrain from treatment or stop tattooing immediately.

5.4.1 Contraindications

Tattooing is **not** permitted in case of the following:

- Hemophilia or other blood coagulation disorders
- Current consumption of blood thinners (e.g. acetylsalicylic acid, heparin, aspirin, warfarin)
- Uncontrolled diabetes mellitus
- Any form of active acne in the skin region to be tattooed
- Dermatoses (e.g. skin tumors, keloids or extreme inclination for keloid formation, solar keratosis, warts and/or moles) in the skin region to be tattooed
- Open wounds and/or eczema and/or skin rashes in the skin region to be tattooed
- Scars in the skin region to be tattooed
- Systemic infections and infectious diseases (e.g. hepatitis A, B, C, D E or F; HIV infection) or acute local skin infections (e.g. herpes, rosacea)

- During chemotherapy, radiotherapy or high-dosage corticosteroid therapy (recommendation: less than four weeks before the beginning until four weeks after the end of the therapy)
- Up to twelve months after plastic surgery in the skin region to be tattooed
- Up to six months after filler injections in the region to be tattooed
- Under the influence of alcohol and/or drugs
- Pregnancy and lactation

Treatment of mucous membranes and eyeballs is strictly prohibited.

The treatment must be terminated immediately in the event of:

- Excessive sensations of pain
- Fainting / dizziness

5.4.2 Side effects

In some cases, minor side effects can appear during and after the tattooing process, as described below.

Frequent:

- Local bleeding in the region of the skin surface to be tattooed
- Pain and discomfort on the day after tattooing
- Temporary inflammatory reactions, erythema and/or edema up to 6 days after tattooing
- Skin irritations (e.g. itching or heating), which normally wear off during the first 12 to 72 hours after the tattooing process
- Scabbing, which normally recedes within the first 5 days
- Temporary flaking of the skin, which normally wears off within 8 days

Rare:

- Formation of blisters of the herpes-simplex virus type I (HSV-I)
- Formation of small pimples or skin eruptions if skin is not cleaned carefully after the tattooing process
- Hyper-pigmentation with body's own pigments, in particular on dark skin types, but which disappear completely within a few weeks
- Long-term inflammatory reactions, haematomas, erythema and edema lasting longer than 6 days
- Retinoid reaction (slight irritation up to peeling of skin)
- Possible warming of the pigmented area when exposed to PET and MRT radiation

Please advise your clients to avoid contact with recently treated skin as much as possible. Recently treated areas of skin should also be

- protected against contamination and
- UV radiation and sunlight

Additional stimuli, such as

- swimming pool or sauna visits,
- abrasive or chemical peels,
- hair removal at the treated areas or
- self-tanning lotions

should be avoided by the client in the first two to three days after the treatment.

The needles and needle cartridges are made of stainless steel, which contains 8 to 10.5% nickel. To date it is unknown whether tattooing with such needles might cause an allergic reaction. However, because there have not been any conclusive tests, we recommend that people with a nickel allergy discuss tattooing with their treating physician in advance or even to refrain from tattooing altogether.

5.5 Required qualification

The user requirements of the tattoo machine to be used apply.

5.6 Intended use - requirements for safe use

The treatment must be performed in a dry, clean and smoke-free environment, and under hygienic conditions. The device must be prepared, used and maintained in the manner described in this operating manual. In particular, the applicable provisions for workplace layout must be observed, and the materials to be used must be sterile.

Intended use also includes thoroughly reading and understanding this operating manual, in particular the chapter 5 on page 20.

The intended use exclusively includes the following consumer groups: persons of lawful age who are in a good state of health.

Unintended use is defined as using the device or its accessories in a way other than as described in this operating manual, or failing to comply with its operating conditions. Treatment of contraindication in particular is prohibited.

6 Inserting or changing needle cartridges

WARNING

Risk of injury from needles

Injuries caused by contaminated needles of the needle cartridges can lead to the transmission of diseases.

- ▶ Only use original needle cartridges. The safety membrane installed in the needle cartridges prevent body fluids and pathogens from entering the tattoo machine.
- ▶ Never hold the needle cartridge by its tip or the bayonet connector.
- ▶ Turn off the tattoo machine before changing the needle cartridge.
- ▶ When removing a used needle cartridge, ensure that no ink remnants can run into the grip.
- ▶ Never press the needles out of the needle cartridge.

- ▶ Check while removing a used needle cartridge that the needles are completely retracted into the needle cartridge.
 - ▶ Dispose of used needle cartridges that are no longer needed for the current application properly in a puncture-proof container (sharps container) in accordance with the regulations that apply in your country.
 - ▶ The needle cartridges are delivered in sterile packaging. Do not remove them from their packaging until immediately before you intend to use them.
 - ▶ Always set the tattoo machine down so that the needle cartridge is not on it.
 - ▶ Seek medical attention if injured by a contaminated needle.
-
- ▶ Turn the tattoo machine off completely.
 - ▶ Insert the needle cartridge in the opening in the grip.
 - ▶ Turn the needle module clockwise up to the stop.
 - ▶ Pull carefully to check whether the needle module is firmly anchored in the grip.
 - ▶ To remove the needle cartridge, turn it counterclockwise and remove it from the grip without touch the bayonet connector or the shaft.

7 Filling the needle cartridge

⚠ WARNING

Risk of infection and side effects from impermissible or contaminated inks

If inks are introduced into the skin that are not intended for a tattoo, or the sterility or antiseptic qualities of which is not guaranteed, this may cause infections or other potential side effects.

- ▶ For each treatment, only use antiseptic and sterile inks that have been tested and approved for injection into human skin.
- ▶ Take note of the applicable regulations in your country when selecting the inks.
- ▶ If using ink cups as ink storage to fill the needle cartridges, only use sterile ink cups. The ink cups must be disposed of after each treatment.

NOTICE

Product damage from hitting the cup sides

When dipping the needles into the ink cup, the sensitive needle tips may be damaged if they hit the sides of the cup.

- ▶ When dipping the needles into the ink cup, make sure that the needles do not hit the sides of the ink cup.
 - ▶ Do not continue to use damaged cartridges.
- ▶ Switch on the tattoo machine.
 - ▶ Dip the tip of the needle cartridge into an ink cup filled with ink so that the tip absorbs the ink.



8 Setting the needle protrusion length

⚠ CAUTION

Risk of injury from excessive needle depth

A large needle depth permits a deep puncture depth. If the needle depth and stitching depth are too deep, this increases the risk of side effects.

- ▶ Select the needle depth depending on the skin condition of the client and on the skin area being treated.

Find the steps to take to adjust the needle depth in the operating manual for your tattoo machine.

9 Operating, transport and storage conditions

	Operation	Transport/storage
Ambient temperature	+15 °C to +35 °C	+15 °C to +25 °C
Relative humidity	30% to 75%	30% to 65%

10 Troubleshooting

The following malfunctions may occur:

Fault	Error	Cause	Rectification
The stitching motion decreases or stops.	The safety membrane no longer works.	The safety membrane is ruptured.	<ul style="list-style-type: none">▶ Carefully remove the grip from the needle cartridge.▶ Contact the responsible specialist dealer or the manufacturer.▶ Check the grip and the tattoo machine for contamination and have them professionally cleaned if necessary.

11 Warranty

With this needle cartridge, you have purchased a high-quality branded product.

For the needle cartridges, we guarantee sterility until the expiration date printed on the packaging, provided it is sealed and packaging is undamaged, and subject to compliance with transport and storage conditions. For complaints relating to needle cartridges, please advise us of the item description and batch number printed on the label.

We do not provide warranty cover in respect of the following types of damage:

- Damage and secondary damage arising from unintended use or failure to comply with the operating manual.

12 Declaration of Conformity

The manufacturer

MT.DERM GmbH
Blohmstr. 37 – 61
12307 Berlin, Germany

hereby declares on their own responsibility that the products:

Product name: **Safety- and capillary cartridges**

Article description: E-Mazz-bbyccdd*

a = C, K

zz = 00 - 99

b/bb = F, L, M, R, S, CL, CM, CR, CS, CO

yy = 00 - 99

c/cc = L, M, SL

d/dd = B, TX

* applies to all packaging sizes

Product name: **Craft cartridges**

Article description: E-Mlzzzza*

a = L, M, R, S

zz = 0000 - 9999

* applies to all packaging sizes

The provisions in the following directives:

Machinery Directive

2006/42/EC

REACH Regulation

1907/2006

UK

Supply of Machinery (Safety) Regulations 2008

The following other standards were applied:

DIN EN ISO 14971:2013-04

DIN EN ISO 11135:2014-07

DIN EN ISO 13485:2016-08

DIN EN 82079-1:2013-06

DIN EN 868-7:2017-05

Medical products - Application of risk management to medical devices

Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

Medical devices - Quality management systems - Requirements for regulatory purposes

Preparation of instructions for use - Structuring, content and presentation - Part 1: General principles and detailed requirements

Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods

Authorized representative for compiling the relevant technical documentation:

Dr. Andreas Pachten, MT.DERM GmbH, Documentation Officer

This declaration is issued on behalf of the manufacturer by:

Berlin, dated 6/3/2022, Berthold Schuler



(Signature of CEO or deputy)

Original

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