



Zusätzliche Fixierung des CGM-Sensors oder Patchpumpe bei Sport und anderen Aktivitäten



starker Halt durch verstellbares Armband mit hohem Tragekomfort



Große Farbvielfalt durch wechselbare Armbänder und Halter








EN

Instruction manual

for DiaBrothers fixation tape for CGM sensors and patch pumps

Please read the complete instructions for use before using the fixing tape for the first time. It contains important information. Please keep the instructions in a safe place as they are part of the product.

Symbols used in these instructions for use and on the label:

	Follow the digital instructions for use		Manufacturer
	Medical device		Date of manufacture
	Keep away from sunlight		Charge
	Keep dry		

Intended use

Additional fixation of a CGM sensor or patch pump to prevent premature falling during activities (e.g. sports). The fixation supports the sensor or patch pump adhesive, which is attached to the user's skin. Sweating or stronger movements can cause the adhesive to come off, causing the sensor or patch pump to fall off and the function to be lost.

User/patient groups

The fixation band can be used by diabetics who use a CGM sensor or a patch pump, and by children with an arm circumference of 15 cm or more, as well as by persons in need of care, where a caregiver can apply and remove the fixation band.

Indications

When additional fixation of a CGM sensor or patch pump is helpful during physical activity (such as sports) in the air or in water.

Precautionary measures

- It is important that the CGM sensor or patch pump can be applied securely before using the fixation tape. If this is not the case, there is a risk that the fixation tape will not be applied correctly due to a lack of knowledge and skills, which may result in damage to or detachment of the CGM sensor or patch pump.
To ensure that the CGM sensor or patch pump is not dislodged due to incorrect handling, you should take special care when applying the fixation tape and make sure that the tape is positioned correctly. It is important that the fixation tape is applied slowly and gently to avoid damage to or dislodging of the CGM sensor or patch pump.
To ensure that the CGM sensor or patch pump are functioning properly, you should refrain from any external influence on the fixation band, as this could otherwise cause it to move. You should also discontinue use of the band if its elasticity diminishes or if there is damage to the mount or the band clips, as in this case the band's fixation function could be compromised and the CGM sensor or patch pump could become dislodged.

Contraindications

The fixation band must not be used in the following cases:

- Skin and tissue damage at the site of application or in the immediate vicinity, such as broken skin, sensitive tissue, rashes, lymphoedema or haematomas.

Circumstances in which sudden movements or external influences could cause the fastening strap to slip or pose a risk of injury, such as during sleep or contact sports.

In the case of conical upper arm shapes, where the fastening strap can easily slip off

In the case of allergic reactions to the materials used.

Dealing with skin irritation

The elastic used consists of 84% polyester and 16% latex. If you have very sensitive skin, this may in rare cases cause a rash, itching or irritation. In this case, remove the strap immediately and do not use it again.

Warnings

- The use of the securing band is at your own risk and no liability is accepted for damage to or loss of CGM sensors or patch pumps resulting from improper use.

- The securing band should only be used on healthy, uninjured skin, otherwise infections may occur. If the fixation band could come into contact with scratches, cuts, burns, sunburn or any rashes or irritations, it should not be worn. In addition, the band should only be used by people without sensitive upper arm restrictions, as otherwise excessive pressure or skin damage due to incorrect application could go unnoticed and lead to inflammation.

If the fixation band is used improperly, it can cause the CGM sensor to provide incorrect readings. It is therefore important that you follow the instructions for applying the fixation band carefully to ensure that it is positioned correctly. If the CGM sensor shows implausible values, you should also check the blood glucose level in the blood to ensure that the readings are correct.

Using the securement tape on heavily creamed or oily skin may cause it to slip, leading to CGM sensor or patch pump dislodgement or inaccurate readings. It is therefore important that the securement tape is applied to clean and dry skin to ensure that it remains securely and correctly positioned.

Do not use the tape to hold other items in place; it is only intended for the CGM sensors and patch pumps for which it is designed.

The tape should not be too loose or too tight. It should be adjusted so that it does not leave marks on the skin.

If you notice any allergic reactions to wearing the restraint strap, you should take the strap off immediately and not wear it again. In such cases, please inform us immediately.

Care

The fixation strap does not require any special care. If it becomes dirty, it can be easily washed in the washing machine at 30 or 40 degrees. The fixation strap then dries very quickly and can be used again.

Storage

The fixation strap should be stored in a cool, dry place, protected from light. The fixation strap should be protected from direct sunlight and water.

Reporting to the manufacturer or the relevant authority

If a serious incident occurs in connection with the fixation tape, please inform us, DiaBrothers, and/or the Federal Institute for Drugs and Medical Devices (BfArM). A serious incident is any event that may have led or could lead, directly or indirectly, to any of the following:

- the death of a patient, user or other person
- a temporary or permanent serious deterioration in the health of a patient, user or other person
- a serious risk to public health

Customer support

You can reach us at:

Email: support@diabrothers.com

Phone: +49 62012498418

Website: <https://www.diabrothers.com/kontakt/>

Website for downloading the declaration of conformity:

<https://www.diabrothers.com/declaration-of-conformity/>

Technical data Arm circumference sizes:

Size S: 15 – 25 cm

Size M: 25 – 35 cm

Size L: 35 – 45 cm

Bandwidth: 20mm

Material elastic band:

84% polyester and 16% latex

Material holder:

TPU, PLA plastic

Durability:

Durability depends on the type and frequency of use.

Risk class:

1, Rule: 1, of Annex VIII, EU MDR

Application of the fixation strap

Step 1

Before each application, check the fixation strap for damage or cracks. The rubber band must be stretchy and not worn out. If the fixation strap is in order, place it below the CGM sensor or patch pump at the wearing site. Never adjust the size directly on the CGM sensor or patch pump, as this can cause the device to move. The fastening band should not be too loose or too tight. It should be adjusted so that it does not leave marks on the skin.

Step 2

The two clips on the strap allow you to easily and conveniently adjust the strap to your perfect size. If the fastening band is too loose or too tight, remove the fastening band and adjust it to the desired size.

Step 3

Once the correct size is set, carefully place the holder over the CGM sensor or patch pump and position the armband so that it does not pull the device downwards.

Wearing the fastening strap

The securing band is suitable for sporting activities such as jogging, swimming, ball sports and much more. In any everyday situation in which you sweat or move around more, the securing band provides additional support for the CGM sensor or patch pump. The securing band can be worn underwater without any problems. The band dries very quickly.

Removing the securing band

If you no longer wish to wear the fixation band, you can carefully lift the plastic holder off the CGM sensor or patch pump and then remove the entire fixation band.

Disposal

If you wish to dispose of the fixation band, you can do so in the residual waste or recycling bin.