

Instructions for use

Please read these instructions carefully before use.

Of course, there are personal differences. In the end, everyone will find their optimal duration of the heating time for themselves. The contact pressure also depends on the physical constitution of each individual.

Trading Name

Thermal pressure plate for stoma care products

Intended Purpose

The thermal pressure plate improves the adhesion of two-part stoma devices to the skin surrounding the stoma.

Indications

Permanently created terminal enterostoma

Causal indications for an enterostoma include carcinoma of the abdomen, Crohn's disease, familial adenomatous polyposis (FAP), organ malformations, and accidents.

Permanently placed terminal urostoma as conduit, continent colostomy (pouch)

Causal indications for a urostomy include congenital malformations, atresia, stenosis of the urinary tract, nerve damage, tumors, consequences of radiation therapy, injuries.

Indications after consultation

Patients with the following medical conditions and body reactions should consult their attending physician and/or ostomy therapist before using the thermal pressure plate:

- Hypersensitive reactions to pressure and temperature or allergic reactions to the material used.
- hernia; parastomal hernia and subcutaneous prolapse
- increased intra-abdominal pressure
- dermatoses (e.g. psoriasis, dermatitis ulcerosa, toxic dermatitis, superinfection)
- Parchment skin
- adhesive intolerance (contact dermatitis) > change supply beforehand
- Stoma in the field of radiation therapy

Contraindications

- ureteral fistula (cystostomy), parastomal fistula
- terminal stoma with prominent position over 2 cm or prolapse

The thermal pressure plate is not applicable if the prolapsed bowel cannot be relocated back into the abdominal cavity without problems. This may be the case, for example, with adhesions, if the passage channel in the abdominal wall is too narrow or if there is a small bowel stoma. In these cases, a physician and/or an ostomy therapist should be consulted.

Risks of use

In the event of acute bleeding in the area of the stoma due to low TBZ or Quick values, the thermal pressure plate should only be used after consultation with the attending physician.

Adverse side effects

None known

Intended users

Patients with the appropriate indication as personal users, as well as caring nursing staff / family caregivers, after successful instruction by the physician or ostomy therapist.

Expected clinical benefit

The thermal pressure plate improves the adhesion of the stoma systems and thus grants increased safety that the plate does not come off prematurely, unintentionally or during stronger physical activities.



Thermische Andruckplatte in der Schutzverpackung



Thermische Andruckplatte, Ansicht von der Stomaseite



Thermische Andruckplatte, vor dem Auflegen auf die Basisplatte



Thermische Andruckplatte, auf die Basisplatte aufgelegt

Performance features

The thermal pressure plate in the temperature range between 40°C and 35°C positively influences the adhesive properties of the supply adhering to the skin, so that its adhesiveness increases. The various supply systems generally use adhesives that acquire a viscous (honey-like) consistency when heated and then solidify again when cooled. Cooling of the hot-melt adhesive causes the polymer chains to approach each other, thus limiting their mobility. Physical interactions form between them, which determine the degree of cohesion (force of attraction).

Before Use

For your supply with or without a locking ring, please check whether the size of the thermal pressure plate matches the base ring system used and the size of the stoma.

Pay attention to whether any lime scale is visible on the thermometer. If this is the case, perform maintenance: Release the black retaining ring from the retaining groove by applying light pressure on one side. Then remove the thermometer and lightly rub off any limescale coating under the thermometer with a microfiber cloth under running water.

Instructions

Your hands must be clean, dry and free of grease.

Heat the pressure plate to 40 - 42°C in a warm water bath or under a flowing stream of hot water. The temperature can be seen on the built-in thermometer. It should be noted that a temperature higher than 42°C is not recommended, as it may lead to reduced adhesion.

Place the thermal pressure plate with the thermometer side on a firm base and ensure that the foam pad supplied is placed between the base and the thermal pressure plate to prevent premature cooling of the pressure plate during the heating process. If necessary, the stoma base plate must be adapted to the stoma before heating. This adaptation is performed by cutting according to the specifications of the base plate manufacturer.

During heating of the new stoma base plate to be used, the stoma and the surrounding areas are to be cleaned according to the care instructions. Make sure that the skin surfaces around the stoma are clean, grease-free and dry before applying the new fitting.

Skin protection paste to even out scars or large irregularities should be used sparingly as needed, according to the manufacturer's instructions.

Please check now whether the preheated supply is flexible enough and remove the adhesive protection foil according to the manufacturer's instructions.

Now you can apply the supply over the stoma according to the manufacturer's application instructions and care instructions. Please reheat the thermal pressure plate to 40°C with warm water.

In the next step, please press the thermal pressure plate with the side opposite the thermometer, i.e. the cutout for the locking ring of the bag, evenly onto the base plate at your own discretion for approx. 4 min.

During the pressing process, the heat is transferred from the pressure plate via the stoma base plate to the abdominal wall and the temperature conditions are equalized. The now warm and flexible adhesive surface is pressed evenly and without wrinkles onto the skin. At particularly sensitive points around the stoma, it may be necessary to press the adhesive surface again by hand.

After the pressing time and an appropriate cooling down, according to experience to approx. 35°C, the adhesion process should be completed so that the pouch can be locked into position.

When using the thermal pressure plate for attaching stoma care devices, every patient will soon find out which temperature, which time and which pressure intensity are the most effective for them.

Now you can clean or disinfect the thermal pressure plate according to the instructions.

Any excretions occurring during the application of the restoration may affect the adhesive behavior, so these must be removed immediately. The replacement cycle should be carried out in such a way that no excretions are to be expected.

Maintenance

At intervals of 4 to 5 weeks, release the black retaining ring from the retaining groove by applying slight pressure on one side. Then remove the thermometer and lightly rub off any lime scale under the thermometer with a microfiber cloth under running water.

Disposal

The disposal of the thermal pressure plate occurs as part of the local resource recycling process, as aluminum scrap, stainless steel scrap and plastic product.

The service life of the product is at least 5 years.

This instruction was updated on 07.06.2021.

Notice

All serious incidents related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

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