

eXaSkin Plus®

Instructions for Use

Identification of eXaskin

Brand Name: eXaSkin PLUS 150 and eXaSkin PLUS 225

References of eXaSkin:

Reference	UDI-DI	Brand name	Component A (Paste)	Component B (Catalyzer)
AG1001003-150	8436591051961	eXaSkin PLUS 150	AG1001003-150p (6 pcs of 150 gr)	AG1001003-150c (6 pcs of 4 gr)
AG1001003-225	8436591051954	eXaSkin PLUS 225	AG1001003-225p (5 pcs of 225 gr)	AG1001003-225c (5 pcs of 5,6 gr)
AG1001003-650	8436591052937	eXaSkin PLUS 650 Breast	AG1001003-650p (2 pcs of 650 gr)	AG1001003-650c (2 pcs de 16,25 gr)

Description: High-density bolus and Immobilization submask.

Manufacturer:



Anatomical Geometry, S.L.
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Class: Medical Device, non-sterile (93/42/EEC)



Intended purpose

eXaSkin PLUS can be used in 2 different intended purposes:

- High-density bolus for radiotherapy treatments.
- Immobilization submask for radiotherapy thermoplastics masks.

Presentation

eXaSkin Plus 150 contains 6 kits of product and a Wax paper. Each kits contains:

- 1 eXaSkin Putty aluminum bag of 150 g (**Component A** -Lilac colour Putty-).
- 1 eXaSkin Catalyzer tube of 4 g (**Component B** -Red colour Putty-).

eXaSkin Plus 225 contains 5 kits of product and a Wax paper. Each kits contains:

- 1 eXaSkin Putty aluminum bag of 225 g (**Component A** -Lilac colour Putty-).
- 1 eXaSkin Catalyzer tube of 5,6 g (**Component B** -Red colour Putty-).

eXaSkin Plus 650 Breast contains 2 kits of product and a Wax paper. Each kits contains:

- 1 eXaSkin Putty aluminum bag of 650 g (**Component A** -Lilac colour Putty-).
- 1 eXaSkin Catalyzer tube of 16,25 g (**Component B** -Red colour Putty-)

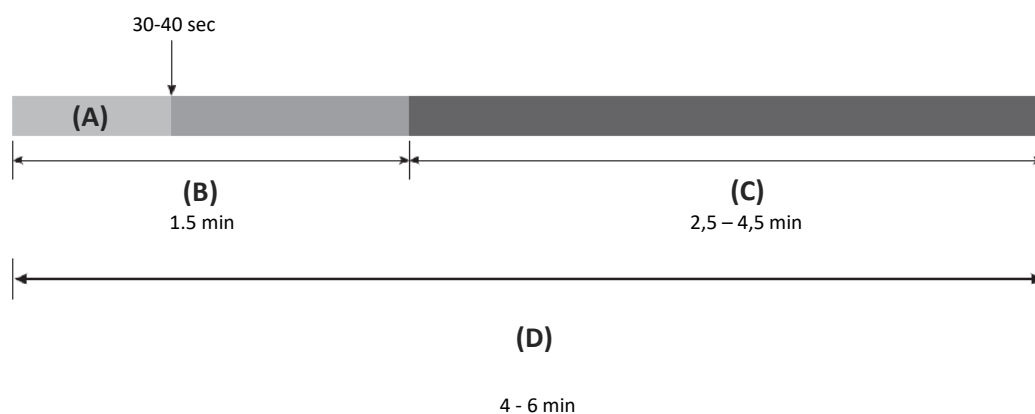
How to use

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Working Times Table

Times	1	2	3	4
eXaSkin	Mixing Time (A)	Total Working Time (B)	Time on skin (C)	Setting Time (D)
	30 - 40 sec	1,5 min	2,5 – 4,5 min	4 - 6 min



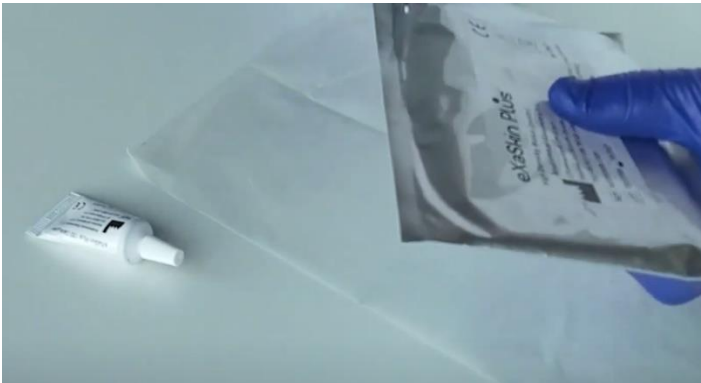
Preparation of an eXaSkin layer

The next steps should be followed, being very important to **carefully watch the Working Times** (check the table above):

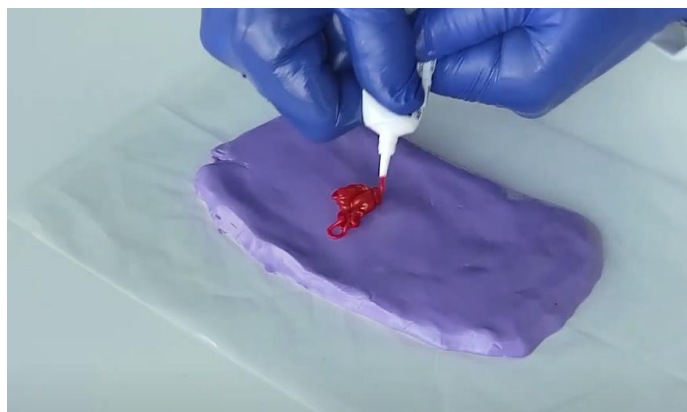
1. Open the mold and place the **wax paper sheet**, as shown in the figure bellow.



2. Open the sealed aluminum bag using scissors if necessary.



3. Extract the putty (**Component A**) and place it on the wax paper. Open the tube (**Component B**) and place the red paste on the putty. **MAKE SURE TO GET ALL THE RED PASTE OUT OF THE TUBE.**



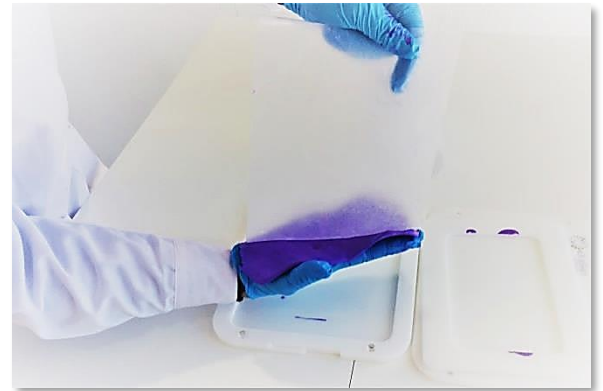
4. **Knead it energetically by folding it over onto itself.** Repeat this operation until the mix is homogenous, without any stripes (**A: Mixing Time¹: 30 - 40 sec.**). It is highly recommendable to use a clock to control the Working Times.



5. Place the mixture on the wax paper sheet inside the mold and spread it evenly along it. Close the mold and press the mold's lid to get a homogeneous eXaSkin layer.



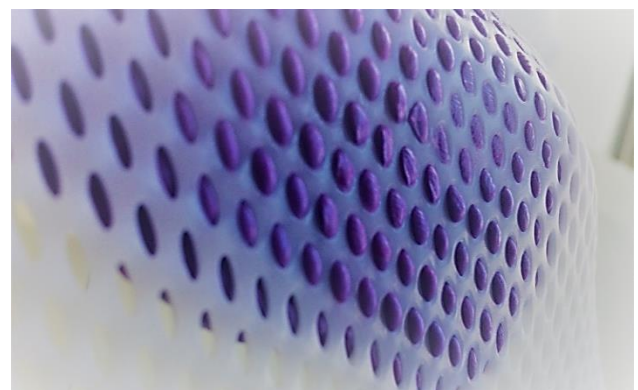
6. Open the mold, extract the eXaSkin layer and remove the wax paper sheet (**B: Total Working Time²: 1,5 min.**).



7. eXaSkin is ready to be placed on the treatment area and to be adapted to the skin shape. The **hardening process** takes from 2,5 to 4,5 min. (**C: Time on Skin**). Next, proceed with the planning CT with the eXaSkin layer placed on the area of interest.



8. If eXaSkin is used as **SUBMASK**, once the wax paper sheet is removed, open a central hole in the layer to allow patient breathing, place the layer on the patient's face, and take and fix the layer ends to the ears (see picture below). Finally, adapt eXaSkin to the skin shape and immediately place a thermoplastic mask on the patient's face. **IMPORTANT**: the thermoplastic mask has to be heated prior to start the process of eXaSkin preparation.



RECOMENDATIONS.

- 1.- **Mixing Time (A) must never be under 30 sec. Even if it seems the mixture is properly done, it is important to keep on mixing in order to assure the homogeneous distribution of the catalyst.**
- 2.- **Total Working Time (B) should not exceed 1,5 min.**

Storage, expiration date and disposal



Store between 5 y 27 °C.

The expiration date is printed on the label.

Once the treatment is finished, disposal have to be executed according the applicable law.

Once the bolus has hardened on the surface, store in a position that does not alter its shape. Do not place objects on top or stack them on top of each other.

Warnings



- Use only by qualified personnel.
- The use of gloves is recommendable. Prevent Component B from coming into contact with skin and eyes, wash well with soap and water in the event of accidental skin contact. In the event of eye contact, rinse thoroughly with running water and seek medical attention. If any of the components are ingested, seek medical attention.
- Avoid contact with hair and textiles.
- Multiple use-single patient medical device: the eXaSkin layer will not adapt properly to the new patient.
- In sensitive subjects, polysiloxane may cause irritation or other allergic reactions.
- In case that a serious incident that has occurred in relation to the device should be reported to Anatomical Geometry and the competent authority of the Member State in which the user and/or patient is established.
- **EXASKIN LAYER MUST NEVER BE OVERRIDED AS IT IS ROUTINELY DONE WITH SILICONE BOLUS. THE DATA ABOUT EXASKIN LAYER DENSITY, SHAPE AND THICKNESS IS DIRECTLY OBTAINED BY THE TREATMENT PLANNING SYSTEM FROM THE CT IMAGES.**