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STERILE EO      +25 °C

Nur für Applikator | Only for applicator |
Solo para aplicador | Somente para aplicador |
Solo per applicatore | Seulement pour applicateur |
Только для аппликатора | Aplikator için:

CE 2292  

CLUSTO-Prick®



www.clusto-prick.com

EU REP

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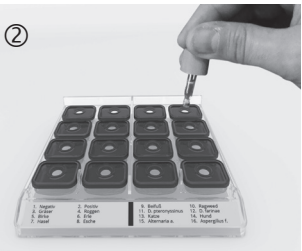
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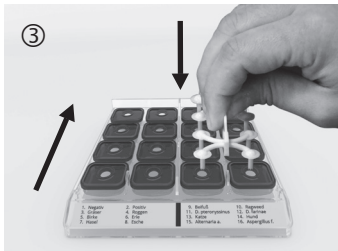
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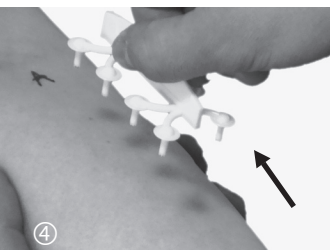
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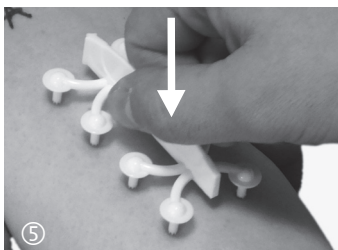
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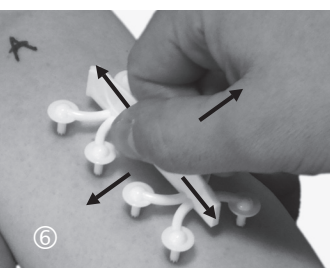
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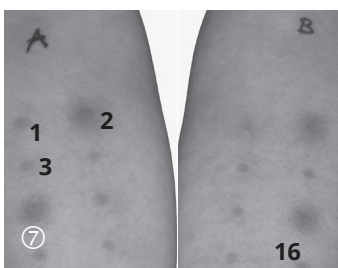
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CLUSTO-Prick®

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Instructions for Use – Read carefully!

The system CLUSTO-Prick® consists of a container with a protective cover and 16 integrated reservoirs which are used for the allergen solutions and the controls (from pipet bottles) as well as CLUSTO-Prick® applicators with eight skin prick tips each (see ①). Fourteen allergens and two controls can be tested with two applicators in one run.

Each CLUSTO-Prick® applicator is in a sterile package and **for single use only**. Applicators should be always disposed after use. Do not use any CLUSTO-Prick® applicator after the expiry or if the package is damaged.

Filling

Take the container out of its package. Do not use a damaged or opened package. Stick a label indicating the allergens onto the respective area at the front side of the container.

Before each refilling of allergen solutions from pipet bottles with different expiry or once per year at least, perform a regeneration of the container like described at page 12.

Fill the reservoirs of the container with the allergen solutions (from pipet bottles with a maximum content of 2.5 mL) in accordance with the label at the front side of the container (see ②). Compare with the labels on the respective pipet bottles in order to avoid mix up. Transfer the allergen solutions with the dropper pipet until the pipet bottle is completely empty. Normally after filling, the content in the reservoirs lasts up to 150-200 CLUSTO-Prick® test runs. Notice that the content in different reservoirs will not be necessarily evenly consumed.

Store the container with its protective cover in the fridge (+2 °C to +8 °C). You can stack up to three containers.

Preparation

Take the container out from the fridge 15 minutes before use. Check all reservoirs for sufficient content to make sure that both CLUSTO-Prick® applicators can dip completely into the allergen solutions. Inspect the filling levels preferably from below.

Take out two CLUSTO-Prick® applicators from their packaging immediately before using them. Put the applicators into the filled container (see ③). When immersing the applicator make sure that

the arrows on the grip toward the letters „A“ as well as „B“ at the upper side of the container. The applicator has to fit properly in the reservoirs.

Administration

Always check the patient's suitability for the skin prick test and inform about the performance. It is **necessary** to consider the required wash-out periods of administered medicinal products that may inhibit the skin reaction.

Choose suitable uniformly **flat** skin areas at the volar sites of both patient's forearms. Mark both skin areas above with „A“ and „B“ in accordance to the two CLUSTO-Prick® applicators. If required remove residues from the skin (e. g. by disinfection).

Hold the patient's right forearm with one hand. Place forearm and hand on an even firm underlay. With the other hand, take the CLUSTO-Prick® applicator (A) from the left side of the container. Hold the CLUSTO-Prick® applicator horizontally at the center of the grip. Please avoid any unilateral inclination in any direction as well as contact to foreign substances, especially at the skin prick tips wetted with allergen solution. The arrow at the grip of the CLUSTO-Prick® applicator has always to point upwards to the patient's upper arm as well as the letter „A“ marked before (see ④).

Put the CLUSTO-Prick® applicator uniformly onto the skin area chosen before to transfer the allergen solutions. Make sure that **all** eight skin prick tips have direct contact to the skin!

Push the CLUSTO-Prick® applicator at the center of the grip into the skin **firmly** and **deeply**. The six small teeth on the eight skin prick tips of the CLUSTO-Prick® applicator have to puncture into the epidermis about 1 mm by the integrated depth control and transfer the allergen solutions (see ⑤).

Perform four **tilting** motions (to the left, right, up and down) with the further pushed CLUSTO-Prick® applicator in order to widen the application area and to achieve an optimal provocation in the epidermis by all eight skin prick tips (see ⑥).

During the entire application within **6 to 8 seconds**, the fixed pressure exerted with the CLUSTO-Prick® applicator must be retained **constantly!**

Afterwards, remove the CLUSTO-Prick® applicator slowly from the skin area and dispose of it.

Repeat the steps explained above with the CLUSTO-Prick® applicator (B) from the right side of the container at the patient's left forearm.

In exceptional case, you may use CLUSTO-Prick® applicator on two flat places on the back.

Store the container with its protective cover until its next use in the fridge (+2 °C to +8 °C). You can stack up to three containers.

Evaluation

Observe the patient for at least 30 minutes. Ask the patient to inform you immediately in case of any unexpected side effect. Have sufficient emergency supplies ready.

Start the evaluation 15 minutes after administration of the allergens.

Dab the tested skin areas to remove remaining allergen solutions.

Evaluate the reactions of the negative control (Negative, NaCl) and of the positive control (Positive, histamine) at the patient's right forearm at respective test fields no. 1 and 2 (see 7). The negative control must not show any reaction or a reaction with a mean wheal diameter of less than 2 mm. The positive control has to show a mean wheal diameter of at least 3 mm. Only in this case the other test results are evaluable.

Determine the mean wheal diameter for every test field (no. 3 - 16) at both patient's forearms.

Consider the following scheme to evaluate each skin reaction regardless of the reaction of the positive control (Positive, histamine):

Assessment	Documentation	Mean wheal diameter in mm
Negative	∅	0
Questionable	(+)	< 3
Positive	+	≥ 3 to < 4
	++	≥ 4 to < 5
	+++	≥ 5 to < 6
	++++	≥ 6

For documentation of the results fill-in the available report sheet completely.

Interpret the test results always in consideration of anamnesis and medical history.

The test has to be repeated in case of positive results despite negative reaction of the positive control (no relevant histamine reaction).

If the question arises, in addition to the usual immediate evaluation, another can be performed and documented, e. g. after 6 up to 8 hours.

Notice

Necessarily, pay attention to the correct insertion of the CLUSTO-Prick® applicator into the container. To avoid any contamination, dispose a CLUSTO-Prick® applicator in wrong position and therefore not correctly inserted and replace it with a new one.

Secondary literature

Bousquet J et al. Practical guide to skin prick tests in allergy to aeroallergens. Allergy 2012;67:18-24

Regeneration of the container

Regeneration of the container can be performed at the times specified on page 9:

After discharging the remaining allergen solutions, wash the container with mild dish soap in a sink or without cleanser in a commercial dishwasher. Afterwards rinse the container with distilled water and then air dry. Alternatively, a steam sterilisation (at 121 °C and 2 bars pressure for 20 minutes) can be performed.

If required, replace the label at the front side of the container after regeneration with a new one.

Advice for disposal

Additional to paper, carton and cardboard, used material for the individual parts are:

CLUSTO-Prick® applicators:

Acrylnitril-Butadien-Styrol-Copolymer (ABS)

Primary package of CLUSTO-Prick® applicators:

Polystyrol (PS) and film made of composite material

Container:

Cycloolefin-Copolymer (COC)

Primary package of the container:

Polyethylenterephthalat/Polypropylen (PET/PP)

Ordering information

REF	08251026	Package with 10 CLUSTO-Prick® applicators in individual sterile packing
	08251032	Package with 100 CLUSTO-Prick® applicators in individual sterile packing
	08251084	Container with 16 integrated reservoirs and protective cover, without labels

Instrucciones de uso – Lea cuidadosamente

El sistema CLUSTO-Prick® consiste en un contenedor con una cubierta protectora y 16 depósitos integrados que se utilizan para las soluciones alergénicas y los controles (a partir de viales cuentagotas), así como en aplicadores CLUSTO-Prick® de ocho puntas para prueba cutánea (ver ①). Con dos aplicadores se pueden probar catorce alérgenos y dos controles en una sesión.

Cada aplicador CLUSTO-Prick® se presenta en un paquete estéril y **para un solo uso**. Los aplicadores deben desecharse siempre después del uso. No utilice ningún aplicador CLUSTO-Prick® después del vencimiento o si el paquete está dañado.

Llenado

Saque el contenedor de su envase. No utilice un envase dañado o abierto. Pegue una etiqueta adjunta en el área respectiva en la parte frontal del contenedor.

Antes de cada recarga con soluciones alergénicas a partir de viales con cuentagotas con diferente vencimiento o, al menos, una vez al año, realice una regeneración del contenedor tal y como se describe en la página 18.

Llene los depósitos del contenedor con las soluciones alergénicas (a partir de los viales con cuentagotas con un contenido máximo de 2,5 mL) de acuerdo con la etiqueta frontal del contenedor (ver ②). Compare con las etiquetas de los viales respectivos para evitar confusiones. Transfiera las soluciones alergénicas con el cuentagotas hasta que el vial esté completamente vacío. Normalmente, después del llenado, el contenido de los depósitos dura para 150-200 pruebas CLUSTO-Prick®. Tenga en cuenta que el contenido de los diferentes depósitos puede no consumirse necesariamente de manera uniforme.

Guarde el contenedor con su cubierta protectora en la nevera (2 °C a 8 °C). Puede apilar hasta tres contenedores.

Preparación

Saque el recipiente de la nevera 15 minutos antes de usarlo. Verifique que todos los depósitos tengan suficiente contenido para asegurarse de que ambos aplicadores CLUSTO-Prick® puedan sumergirse completamente en las soluciones alergénicas. Inspeccione los niveles de llenado preferiblemente desde abajo.