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Rx Only (for U.S.)



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ALUMIN. DIC-0014 R 2

ENGLISH

Finn Chambers on Scanpor

Indications for use:

Finn Chambers on Scanpor are intended for use in epicutaneous diagnostic patch testing and clinical research by or under the supervision of a trained healthcare professional only.

Contraindications:

Confirmed Type IV hypersensitivity to aluminum.

Warnings and Precautions:

- Use polypropylene coated chambers if testing with an aqueous mercuric solution.
- Do not cut strips between the chambers, as the remaining adhesive area may be too small.
- Use caution when administering uncommon test substances and selecting their test concentration.
- Apply patch test panels on healthy, clean skin only. Instruct patients to refrain from showering or excessive sweating, as the panel adherence may be compromised.
- See adverse events section for more warnings.

Special Patient Populations:

Finn Chambers on Scanpor can be used in all patients consistent with the limitations associated with the use of individual allergens and patch testing in general.

Adverse Events:

- Allergic reactions to aluminum and Scanpor tape are very rare.
 - However, occasional cases have been reported.
 - Skin may react to the removal of the tests with a slight mechanical irritation, indicated by erythema.
- Instructions for Use:**
- Identify each panel and chamber being used for the patch test (numbers).
 - Remove the protective paper backing to reveal the chambers, leaving the narrow handling strip in place for easiest application onto the patient.
 - *Semisolids: apply directly into the chamber.*
 - *Liquids: use filter paper discs to absorb the liquid being held in the chamber. Note: Do not let the paper discs dry, as this could result in a false negative reaction.*
 - Apply the liquids and volatile substances immediately prior to application on the patient.
 - Apply the panels on the patient's back, or suitable alternate location.
 - Apply the panel starting at the bottom and working upwards pressing each chamber in place and working out any air trapped between the tape and skin.
 - Remove the remaining paper-backing ensuring the entire panel is sticking to the patient's back.
 - Mark the placement of the panels on the skin.
 - At removal, each test site should have a ring-shaped depression. This verifies occlusion during the patch test.
 - Allow 20 minutes for transient erythema to dissipate, prior to reading initial results.
 - Discard the used panels in accordance with local regulations.

Serious Incidents:

Report all serious incidents:

In the USA: to the manufacturer and the FDA;

In the EC: to the European Representative, or local competent authority.

In other countries: to the distributor or local competent authorities.

Revised: 1/2020

中文

Finn Chambers on Scanpor

使用说明

FinnChamber Scanpor斑贴器仅供受过培训的医疗专业人员或其监督下用于皮肤诊断斑贴测试和临床研究。

禁忌症:

已确认对铝过敏 (IV 型)。

警告和注意事项:

- 如果使用汞水溶液进行测试, 请使用聚丙烯涂层的腔室。
- 切勿在斑贴小室之间剪切贴片, 因为剩余的粘合剂区域可能太小。
- 使用不常见的测试物质和选择其测试浓度时请小心谨慎。
- 仅将斑贴测试贴片贴附在健康、洁净的皮肤上。
- 指示患者避免淋浴或过度出汗, 因为贴片的粘性可能会受到影响。
- 请参阅“不良事件”部分以获取更多警告信息。

特殊患者群:

总的来说, FinnChamber Scanpor 斑贴器可用于所有患者, 与个体过敏原斑贴试验的使用限制一致。

不良事件:

- 对铝和粘合剂的过敏反应很少见。
- 然而, 偶尔会报告过敏反应病例。
- 如果使用汞水溶液或丙烯酸酯单体进行测试, 请使用聚丙烯涂层斑贴器。

使用说明:

- 标记用于斑贴测试的每个贴片和小室 [数字]。
- 取下防护纸以露出斑贴器, 将操作条留在适当的位置, 以便最方便地贴在患者身上。
- 半固体: 直接涂抹于斑贴器。
- 液体: 注意: 不要让滤纸盘变干, 因为这可能导致假阴性反应。
- 涂抹液体和挥发性物质之后立即施用于患者。
- 将贴片贴于患者背部, 或其他合适的位置。
- 从底部开始由下至上贴贴片, 将每个斑贴器按压到位并且排出夹在胶带和皮肤之间的任何空气。
- 取下剩余的防护纸, 确保整个贴片贴附于患者的背部。
- 在皮肤上标记贴片的贴附位置。
- 取下贴片时, 每个测试部位都应具有一个环形凹陷区域。
- 在斑贴测试过程中, 这可以验证胶合。
- 在判读初始读数之前, 等待 20 分钟, 让短暂性红斑消散。
- 根据当地法规, 应丢弃用过的贴片。

严重事件:

报告所有严重事件:

在美国: 向制造商和 FDA 报告;

在欧盟: 向欧盟代表或当地主管机关报告;

在其他国家和地区: 向经销商或当地主管机关报告。

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