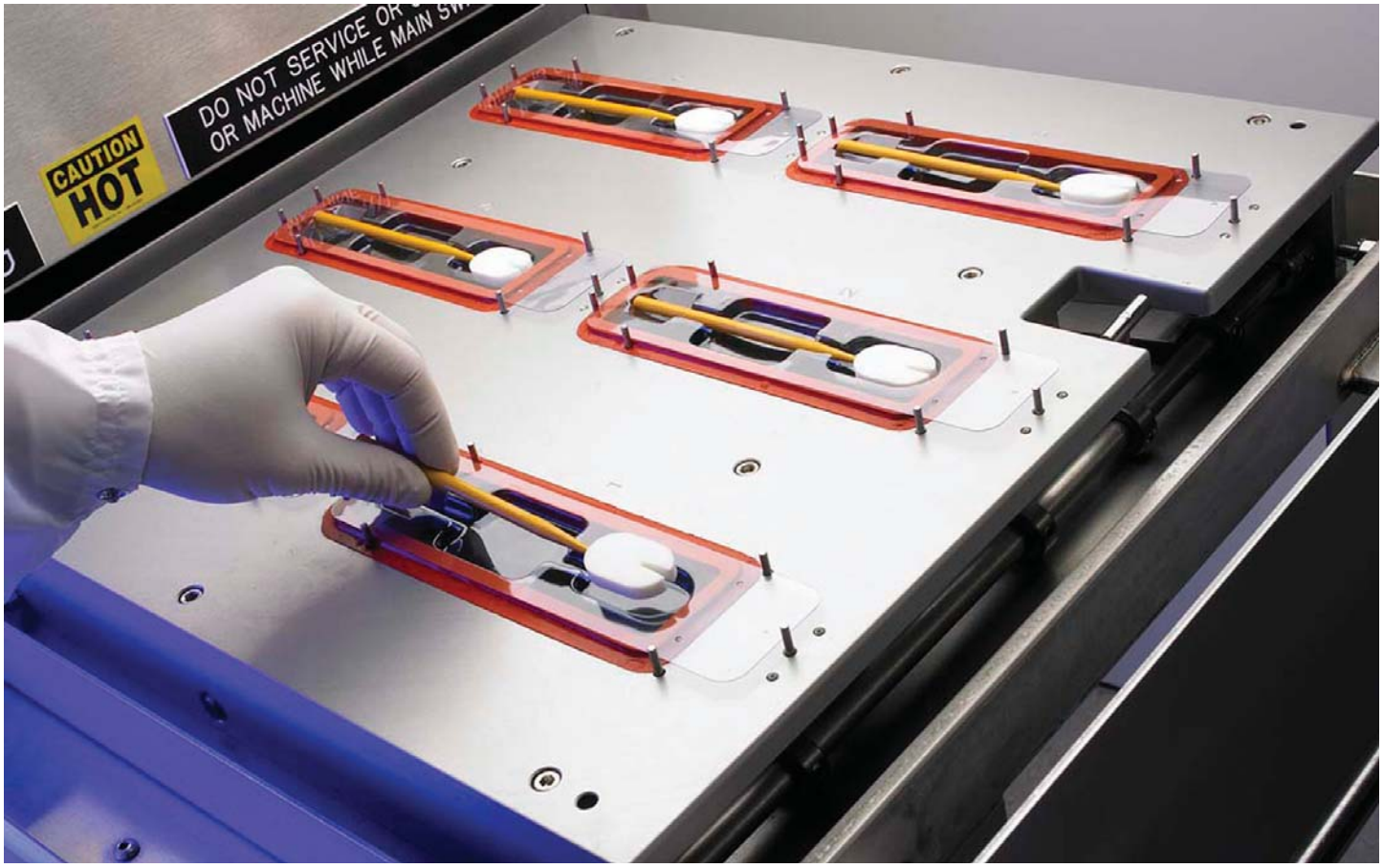

Six cavity medical sealing tray

Don't forget THE PACKAGING

Innovation in medical devices continues apace. There are great ideas out there and a huge amount of work and brainpower are invested in their development. But, don't get caught out by not planning in your packaging project, warns Mark Turner of Medical Engineering Technologies.

The mainstay of packaging standards for sterilised medical devices is ISO 11607 Packaging for Terminally Sterilised Medical Devices.[1,2] This two-part standard details some of the essential requirements for your technical file and submission to the US Food and Drug Administration. It, broadly speaking, asks the following questions:

- Is the sterile barrier packaging material suitable for the task?
- Can it be sealed successfully by the equipment in use?
- Has the reliable performance of the sealing equipment been proven?
- Does the outer packaging protect the sterile barrier packaging in transit and storage?
- Does protection continue throughout the stated shelf to the point of use?

this

Is the sterile barrier packaging material suitable for the task?

This question is posed in the Part 1 of ISO 11607. It is of importance to the project manager/innovator, but it is usually addressed by the material supplier in advance. To identify the correct materials, it suffices to provide the supplier with product details including shape, mass, sterilisation requirements, any moisture retention or exclusion requirements and usage. The supplier should provide data on the material's resistance to microbial ingress, its strength, robustness and integrity, its suitability

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