



Dermal Fillers: Approved & Off-Label Use

JCCP Advisory

The JCCP has been concerned to see reports of harm associated with the use of dermal fillers outside the terms of their intended purpose. Under the UK Medical Devices Regulations (2002) (as amended), manufacturers of medical devices supplied to the UK must be explicit regarding the products intended purpose and the specifications that surround it. In doing so the manufacturer demonstrates, on the basis of extensive evidence, that their products are safe and effective when used as directed. This robust regulatory framework serves to protect public safety. Dermal fillers without CE or UKCA, for which there are no medical claims, have not demonstrated the same level of safety and performance as dermal fillers that are CE or UKCA marked.

The JCCP supports the concept that regulated healthcare professionals may use their clinical judgement, alongside their consideration of the evidence available to determine safe and effective practice, to use medical devices in an off-label context. In making their determination, clinicians should be familiar with the relevant MHRA guidance.

“You should use medical devices as described by the manufacturer in the instructions. If you use the device in any other way, it’s considered ‘off-label’ use. Without the manufacturer’s approval this will be at your own risk and you or your employer could become liable for civil claims for damages from injured patients or their families if something goes wrong with the device.”

www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device

For the purposes of body augmentation significant volumes of a dermal filler are required, the manufacturer of adequately CE/UKCA marked devices must be able to provide evidence that their products are safe to use in this way. It is the JCCP’s experience that dermal fillers that have been used for body augmentation purposes, including for the buttocks and the breasts, are CE/UKCA marked only for facial filling purposes where lower volume is needed. Given the available evidence, the JCCP believes that **the use of high-volume fillers cannot be supported on an off-label basis**. Further, we consider that the following guidance is essential to public safety and legitimate practice.

- Buttock and breast filling procedures are regulated surgical activities. They should only be performed by competent GMC registered surgeons in CQC registered facilities.
- Only dermal fillers CE/UKCA marked for body augmentation purposes should be used for that reason. We note that, where they are so approved, they may be contraindicated for use in the breasts. The JCCP support this approach which reflects the widespread concern surrounding this activity.
- Suppliers of dermal fillers must not promote their products contrary to the terms of the device's intended use.

All providers of dermal fillers must be familiar with the product's Instructions For Use (IFU) that specify the terms of safe and effective use. Any deviation from these terms must be supported by a critical review of the evidence, including wider expert opinion. The JCCP continue to encourage practitioners and members of the public to report any harm, or the potential for harm, arising from the use of any relevant product to the MHRA using the Yellow Card Scheme. This helps ensure the ongoing safety of products used in the cosmetic sector through compliance with post-market surveillance requirements.

This Advisory has been shared with the MHRA to confirm its accuracy.

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