AN INCONVENIENT TRUTH ABOUT CONVENIENCE KITS

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I am going to start this with the truth about sutures. Sutures are excellent for wound closure but are not intended to secure external devices. Look at any instruction for use (IFU) document accompanying a non-absorbable suture, and you will find no reference to securing external devices of any kind. Here is a summary of six IFUs for standard non-absorbable sutures.

As indicated, all are labeled for general soft tissue approximation and/or ligation. Why does this matter? Because of the regulation from the Food and Drug Administration (FDA) Guidance Document, linked here.

Here is a quick breakdown of the logic behind the Convenience Kit Interim Regulatory Guidance (May 1997, last update March 2018). This document was implemented so convenience kits could be assembled and not need separate approval from the FDA to be marketed. The guidance makes sense if all the components in the kit have already been approved. Why would bundling the approved devices together change their functionality?

In the guidance document, this is what is stated about the requirements for the components in the kit.

2. Components
Convenience kits subject to this guidance should only include components that are either: (1) legally marketed preamendments devices, (2) exempt from premarket notification, or (3) have been found to be substantially equivalent through the premarket notification process. The components should be purchased in finished form, i.e., they should be packaged, labeled, etc., consistent with their legal marketing authorization.

The inconvenient truth is that according to this guidance on convenience kits, there should be no confusion that the sutures provided are for wound closure and not to secure an external device. First, however, let us consider giving a grace period for the first few years that this interim regulation was implemented.

In 1997, few engineered securement devices (ESD) were available to replace the gap in securement that sutures had filled since the 1960s. Although, by the last update in 2018, the choices were greater, including a large amount of research on ESD safety and efficacy. Therefore, at this time, there is no reason for sutures to be placed in a central venous access device (CVAD) convenience kit intended to function as securement. Perhaps a sticker placed on current kits explaining there is no securement would get some additional focus on the issue.

In the guidance, CVAD kits are designated under cardiovascular devices. The specific information on these kits can be found in the product classification. Lifted directly from this document is the following definition:

"This product code has been established in accordance with the May 20, 1997, guidance entitled, convenience kits interim regulatory guidance, found at www.Fda.Gov/cdrh/ode/convkit.Html. This type of convenience kit, as listed in the guidance above, is under enforcement discretion, and does not require a premarket notification (510(k)) to market if it meets all criteria in the guidance."

Now that we know that sutures should not be in convenience kits, what can we do? Contact the FDA and ask why they are currently allowing sutures in CVAD convenience kits as a securement device when they have never been marketed or labeled for that function. The regulation falls under the Center for Devices and Radiological Health (CDRH) office and can be found at https://www.fda.gov/about-fda/contact-fda.

Monofilament suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Braided suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Braided Poly suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Braided Silk suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Synthetic Linear Polyolefin suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

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Now that we are on the road to removing sutures as an option for securing any external device, what's next? As vascular access specialists, it is our job to review the research on engineered securement devices to bring the best evidence to the discussion of replacing ineffective and unsafe suture-based securement.

In a recent systematic review of the safety and efficacy of current securement alternatives, the subcutaneous anchor securement system (SASS) significantly limited the incidence of migration and dislodgement associated with CVADs (Bell, et al., 2022).

More randomized control trials focused on the safety and efficacy issues of securement defined in the systematic review will continue to increase the weight of evidence to aid in the optimal securement choice post sutures.

In summary,
1. According to the FDA's guidance documents, sutures must be removed from convienece kits if intended for anything other than wound closure.

2. Your help is needed to contact the FDA with your concerns about the convenience kit guidance allowing sutures to remain in kits intended for securement.

3. Assess the evidence in the systematic review and other peer-reviewed research when choosing an engineered securement device.

4. Consider conducting research on the safety and efficacy of engineered securement devices.

Reference:
Bell, J., Hawes, M.L., Gibson, S.M., & Diloreto, E. Systematic Review of the Safety and Efficacy of CVAD Securement. Journal of the Association for Vascular Access. 2020;27(3):15-35. https://doi.org/10.2309/JAVA-D-22-0013

Median incidence and interquartile range of Migration & Dislodgement

Securement Devices	Number of Studies	Migration & Dislodgement
Adhesive Securement Device	23	9.69 (12.8)
Integrated Securement Device	4	4.17 (8.97)
Subcutaneous Anchor Securement System	13	1.76 (3.47)
Suture Based Securement	22	6.77 (18.4)
Tissue Adhesive	5	(Insufficient data)