

Customer Use Statement regarding Tegaderm with SonoSite Transducers

This statement is intended to address the use of Tegaderm as a sterile cover for FUJIFILM SonoSite Inc. ("SonoSite") transducers.

As an ultrasound transducer manufacturer, SonoSite is responsible for accurately representing acceptable options for sterile covers in the event that it is needed by a clinician. Sterile covers manufactured by CIVCO, for example, are designed, manufactured, and cleared for the specific use of providing a physical sterile barrier between the transducer head and patient's skin. Tegaderm, however, is not indicated for use by the manufacturer, 3M, as a sterile transducer cover/sheath.

Due to numerous factors involved, SonoSite does not recommend Tegaderm as an alternative option to a sterile cover for our transducers and only recommends sterile covers that are indicated for such use by the respective manufacturer.

Any questions can be directed to the Regulatory Affairs department @ ffss-regulatory@fujifilm.com.

Regulatory Affairs Department
FUJIFILM SonoSite, Inc.