



The Closed Herd Bovine Tissue Program

tissue safety, naturally.

The BSE Challenge

The consumption of prion proteins from cattle that suffer from Bovine Spongiform Encephalopathy (BSE or Mad Cow Disease) has been proposed as a potential cause of Human Transmissible Spongiform Encephalopathy Disease (TSE) such as Creutzfeldt Jakob Disease (CJD).

The bovine pericardium that Shelhigh uses in its devices is classified as European Union (EU) Category C (no detected infectivity) – the same category as for milk. Concerns about such cross-contamination in the EU, however, led Shelhigh to cease the sale of its bovine based products into the EU, except in humanitarian use cases where the probable benefit of Shelhigh bovine products outweighed the risk of BSE exposure.

Shelhigh began manufacturing products in porcine pericardia only, a decision that removed any chance of BSE exposure but which also created new challenges (not the least of which was a limit on tissue size due to the significantly smaller porcine pericardium relative to bovine pericardium).

The challenge for Shelhigh was to manufacture bovine tissue products that offered practically zero chance of prion infection from cattle tissue used in its bovine products.

The Closed Herd Solution

Experts in the BSE field agree that the risk of infection among cattle (and therefore to humans) may be practically eliminated through the use of strict ranching and tissue handling procedures. These procedures create a “closed herd” or “BSE negligible risk” group of animals.

Shelhigh has embraced the closed herd solution and has created a comprehensive program that tracks bovine tissue source from the ranch to the end-user.

- ☑ all cattle are from herds that are closed to factors that could introduce the BSE prion agent into the herd.
- ☑ no cattle at the time of certification have been exposed to any source of infection
- ☑ no cattle have an epidemiological link with Transmissible Spongiform Encephalopathy Disease (TSE) cases
- ☑ third-party documentation of BSE Negligible ranching conditions is maintained, including the tracking of cattle and food sources
- ☑ procedures are documented through a comprehensive Hazard Analysis and Critical Control Point (HACCP) system
- ☑ cattle processing plant procedures are integrated with Shelhigh procedures for the proper extraction of bovine pericardium, packing and shipping to the Shelhigh facility
- ☑ Shelhigh closed herd products are identified by the unique trademark bull-in-circle icon (shown at top left of this page)

The Shelhigh Closed Herd Bovine Tissue Program continues Shelhigh’s commitment to surgical solutions that are effective and safe.

Please contact your local Shelhigh representative for more information on our Closed Herd tissue products.



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