Exception/Exemptions
10/2019-9/2020 Fiscal Year

Species: Ovine

Studies:	**Animal Number:**	**Max Duration:**
(b) (4) 032-IS21	6	6 Days

Animals were restrained by a cross ties for up to 6 days of the 14 day study. Prolonged cross-tie restraint was required as these animals had exteriorized device components. Lack of restraint could have predisposed the animals to chewing on the device components and potentially cause displacement of the device. If removed unintentionally (i.e. by chewing or being caught on something), significant to life-threatening hemorrhage could have occurred. Following explant, the animals were no longer required to be cross-tied.

All animals to be used were acclimated to the cross-ties prior to the initial procedure. Animals that failed to tolerate the cross-ties were excluded from the study. The animals were free to stand and lay down but were unable to rotate. Animals were also offered hay *ad libitum* for enrichment and feed.

Species: Bovine

Studies:	**Animal Number:**	**Max Duration:**
(b) (4) 002-IS21	6	30 days

Prolonged cross-tie restraint was required as these animals were anticoagulated using a heparin CRI (via CVL) and had exteriorized device components. Lack of restraint could have predisposed the animals to chewing on the fluid line or device components and/or cause displacement of the device or CRI. If removed unintentionally (i.e. by chewing or being caught on something), significant to life-threatening hemorrhage could have occurred. The animals received a heparin CRI to prevent clot formation that could have increased any bleeding resulting from what would otherwise be minor traumas. This could have led to life-threatening hemorrhage. On the other hand, if the CRI was disrupted (i.e. by chewing or being caught on something) and the coagulation time normalize, the animal could have developed intra-arterial thrombi that could have led to thromboembolism while on study.

All animals to be used were acclimated to the cross-ties prior to the initial procedure. Animals that failed to tolerate the cross-ties were excluded from the study. The animals were free to stand and lay down but were unable to rotate. Animals were also offered hay *ad libitum* for enrichment and feed. Animals were given supervised breaks from cross-tying daily.

Species: Ovine

Studies:	**Animal Number:**	**Max Duration:**
(b) (4) 027-IS16	5	1 day

Prolonged cross-tie restraint was required as these animals were anticoagulated using a heparin CRI (via CVL). Lack of restraint could have predisposed the animals to chewing on the fluid line and caused displacement of the CRI. If removed unintentionally (i.e. by chewing or being caught on something), significant to life-threatening hemorrhage could have occurred. The animals received a heparin CRI to prevent clot formation that could have increased any bleeding resulting from what would otherwise be minor traumas. This could have led to life-threatening hemorrhage. On the other hand, if the CRI was disrupted (i.e. by chewing or being caught on something) and the coagulation time normalize, the animal could have developed intra-arterial thrombi that could have led to thromboembolism while on study.

All animals to be used were acclimated to the cross-ties prior to the initial procedure. Animals that fail to tolerate the cross-ties were excluded from the study. The animals were free to stand and lay down but were unable to rotate. Animals were also offered hay *ad libitum* for enrichment and feed.

Species: Ovine

Studies:	**Animal Number:**	**Max Duration:**
(b) (4)095-IS21	4	48 hours

Prolonged cross-tie restraint was required as these animals were anticoagulated using a heparin CRI (via CVL) and had exteriorized device components. Lack of restraint could have predisposed the animals to chewing on the fluid line or device components and/or cause displacement of the device or CRI. If removed unintentionally (i.e. by chewing or being caught on something), significant to life-threatening hemorrhage could have occurred. The animals received a heparin CRI to prevent clot formation that could have increased any bleeding resulting from what would otherwise be minor traumas. This could have led to life-threatening hemorrhage. On the other hand, if the CRI was disrupted (i.e. by chewing or being caught on something) and the coagulation time normalize, the animal could have developed intra-arterial thrombi that could have led to thromboembolism while on study.

All animals to be used were acclimated to the cross-ties prior to the initial procedure. Animals that fail to tolerate the cross-ties were excluded from the study. The animals were free to stand and lay down but were unable to rotate. Animals were also offered hay *ad libitum* for enrichment and feed.

Species: Ovine

Studies:	**Animal Number:**	**Max Duration:**
(b) (4)004-IS75	8	13 days
(b) (4)005-IS75	7	10 days
(b) (4)006-IS75	4	10 days
(b) (4)007-IS75	8	14 days

Prolonged cross-tie restraint was required as these animals were anticoagulated using a heparin CRI (via CVL) and had exteriorized device components. Lack of restraint could have predisposed the animals to chewing on the fluid line or device components and/or cause displacement of the device or CRI. If removed unintentionally (i.e. by chewing or being caught on something), significant to life-threatening hemorrhage could have occurred. The animals received a heparin CRI to prevent clot formation that could have increased any bleeding resulting from what would otherwise be minor traumas. This could have led to life-threatening hemorrhage. On the other hand, if the CRI was disrupted (i.e. by chewing or being caught on something) and the coagulation time normalize, the animal could have developed intra-arterial thrombi that could have led to thromboembolism while on study.

All animals to be used were acclimated to the cross-ties prior to the initial procedure. Animals that fail to tolerate the cross-ties were excluded from the study. The animals were free to stand and lay down but were unable to rotate. Animals were also offered hay *ad libitum* for enrichment and feed. The animal was given supervised breaks from cross-tying daily.

Species: Ovine

Studies:	**Animal Number:**	**Max Duration:**
(b) (4)398-IS75	1	30 days

Prolonged cross-tie restraint was required as these animals had exteriorized device components. Lack of restraint could have predisposed the animals to chewing on the device components and potentially cause

displacement of the device. If removed unintentionally (i.e. by chewing or being caught on something), significant to life-threatening hemorrhage could have occurred.

All animals to be used were acclimated to the cross-ties prior to the initial procedure. Animals that fail to tolerate the cross-ties were excluded from the study. The animals were free to stand and lay down but were unable to rotate. Animals were also offered hay *ad libitum* for enrichment and feed. The animal was given supervised breaks from cross-tying daily.