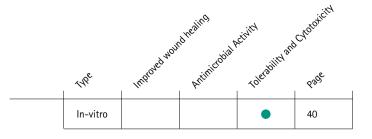
## Askina® Calgitrol® Ag



# Evaluation of Leachable Silver from a Wound Dressing Using the Swine Model

Dr Joseph Carraway and Ms Wendy R. Sharp, NAMSA, Northwood, OH, USA. Report HOSP213 at B. Braun Hospicare

#### Objective

To evaluate the level of silver released from Askina® Calgitrol® Ag, following its application to full thickness wounds in a domestic swine.

#### Protocol - method

Two circular full thickness wounds (2.0 – 2.3 cm diameter; 5–7 mm deep) were surgically induced on the back of a single swine. Askina® Calgitrol® Ag dressings were placed on each wound with the dark side of the dressing against the wound, and held in place with a film dressing, Askina® Derm. At pretreatment (day 0), day 1, 3 and 7, a blood specimen was obtained and the specimen was processed to serum. The serum was analysed for silver by Inductively Coupled Plasma (ICP) Spectroscopy.

#### Results

Under the conditions of the study, the serum levels of silver were comparable at each interval (day1, day 3 and day 7). The highest level detected was 0.008 ppm, at day 7. When compared to the normal human blood levels of silver, this amount is considered insignificant.

Samples	Amount of silver in parts per million ( $\mu g/g$ )
Pretreat	ND
Day 1 (Orange Serum)	0.005
Day 1 (Yellow Serum)	0.005
Day 3	0.002
Day 7 (Dark Orange Serum)	0.008
Day 7 (Light Orange Serum)	0.007
Detection limit	0.001

ND = None Detected

#### Conclusion

Askina® Calgitrol® Ag wound dressings do not result in any significant elevation of silver ions into the blood serum.

### Cytotoxicity study

ISO 10993 Method: Biological Evaluation of Medical Devices, Part 5: tests for Cytotoxicity; in vitro Method guidelines Report HOSP201 at B. Braun Hospicare

#### Objective

This in vitro biocompatibility study was conducted in order to determine the potential for cytotoxicity of Askina® Calgitrol® Ag.

#### Method

A single extract was prepared using single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (IX MEM). A 1:8 dilution of the test extract in IX MEM was placed onto three separate confluent monolayers of fibroblast cells propagated in 5% CO2. After incubation at 37° in the presence of 5% CO $_2$  during 48 h, all monolayers (test, reagent control, negative control and positive control) were examined microscopically to determine any change in cell morphology.

#### Conclusion

Under the conditions of this study, the test extract (Askina® Calgitrol® Ag) showed no evidence of causing cell lysis or cytotoxicity.