# Askina® Calgitrol® Ag

| Type | Improved wound healing | Antimicrobial Activity | Tolerability and Cytotoxicity | Page |
|---|---|---|---|---|
| In-vitro | | | ● | 40 |

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

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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 (µg/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.