

Supporting data for **SilvalGuard™**

INNOVATIVE DEVICE DESIGNED TO PREVENT PIN-TRACT INFECTION (PTI) AND NOSOCOMIAL INFECTIONS ASSOCIATED WITH EXTERNAL BONE FIXATOR, PROTRUDING PINS, AND TUBING AT EXIT SITES.

Metal pins are used to apply skeletal traction or external fixation devices in the management of orthopedic fractures. These pins protrude through the skin (described as 'percutaneous') and the way in which they are treated after insertion may affect the incidence of pin tract infection. ("**Ilizarov System**").

Exit sites of Catheter and Drainage Tubing are similarly affected.

Prevailing prophylactic measures aimed at minimizing the development of PTI and similar infections are:

- i) By means of local disinfection of the site with antiseptic solutions **twice daily**,
- ii) By oral administration of **antibiotics**,
- iii) By additional "**cleansing surgery**" in more severe cases.



Ilizarov System

Despite the above preventative measures, published literature reports the current PTI infection rate at 96.6%

<http://www.amjorthopedics.com/pdfs/037090150e.pdf>, and in other publications a **98% infection rate is reported.**

The effects of these nosocomial and contamination infections can be significantly reduced (1 Log.) by using our novel product; **SilvalGuard™**.

Characteristics

- i) **SilvalGuard™** is easily applied.
- ii) **SilvalGuard™** Significantly reduces exit site infection rates. Research conducted at Tel Hashomer - Sheba Hospital, in Israel, reference <http://euroband.com/SilvalpadResearch.pdf> reveals that by using conventional exit site treatment methods; in 2005 there were **37 infected cases**; whereas after the use of a procedural tray using our system during the years 2006, 2007 and up to September 2008, the total number of infected cases was drastically reduced to **5 infected cases IN TOTAL!**
- iii) **SilvalGuard™** system comprises a silver impregnated dressing (containing 20% silver) that comes into **direct contact** with the skin around the exit site. **Direct contact of silver destroys malevolent microorganisms on site and prevents growth of microorganisms.** Research reveals that silver ions in our dressing were active up to a depth of 40 mm below the epidermis.
- iv) **SilvalGuard™** system facilitates fixation of the silver dressing in direct contact with the skin surface, even in cases where there is a "bridge" over the pin/tubing.
- v) **The active silver dressing can remain in place for a period of up to 7 days (approved by the FDA)** – still enabling medical attendants to lift and observe the exit site and return the dressing after site inspection, - **in comparison** to the current method of treatment that requires disinfecting the site and **twice daily** dressing changes.
- vi) Silver ions are activated when the dressing is moistened- an integral stage in our treatment method. **SilvalGuard™** system is body friendly, air and perspiration permeable, and facilitates moistening.
- vii) Current prevailing methods require additional protection of the exit site when patients **shower**. **SilvalGuard™** system **allows the patient to shower with the dressing in place**, without the danger of infection to the exit site. (In fact, **SilvalGuard™** is more effective when moist!.)
- viii) Preliminary *in vivo* testing of **SilvalGuard™** system revealed that the rate of contamination was reduced by at least one Log. This means a contamination rate of less **than 10%** (compared with a current contamination rate of **96% using conventional methods.**)
- ix) It is estimated that **the cost of current systems in use** (i.e. the cost of two dressing changes per day plus disinfectants and antibiotics [note: the current trend is to minimize use of antibiotics!]) is **20 times greater** than the cost of using **SilvalGuard™***
- x) The new innovative product utilizes known characteristics to combine with a patentable method and product.



7 days in place

* In the U.S. nosocomial infections are not covered by the insurance and the hospitals have to cover these expenses by themselves

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