INTRODUCTION AND OBJECTIVE:
To evaluate the biocompatibility of the InLay Optima® Ureteral stent for mucosal contact for greater than 30 days per the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices.

METHOD:
The purpose of this study was to further qualify the Inlay Optima® stent for a long term indwelling time of greater than 30 days. This was accomplished by following the guidelines and acceptance criteria laid out in the requirement document ISO 10993. Tests were performed by NAMSA, an outside testing laboratory. The tests that were conducted included the following:

- Physico-Chemical USP - A 600 cm² surface of the sample was extracted and tested for nonvolatile residues, residues on ignition, heavy metals and buffering capacity.
- Cytotoxicity Test (Agar Diffusion Method) - Portions of the sample (stent and suture) were tested for cytotoxic reactions in test cell monolayers.
- Vaginal Irritation Study - A saline extract was prepared of the stent material and injected into the vaginal mucosa area of the test subjects. The tissue was then examined for irritation reactions.
- ISO Sensitization Study - The sample was extracted in a solution of sodium chloride and the extract applied topically to test subjects in an attempt to induce sensitization.
- Genotoxicity: Bacterial Reverse Mutation Study - A Salmonella typhimurium and Escherichia coli reverse mutation standard plate incorporation study was conducted to evaluate whether a saline and 95% ethanol extract of the stent would create mutagenic responses.
- Genotoxicity: Chromosomal Aberration Study - The stent was extracted in McCoy’s 5A Media and combined with Chinese Hamster ovary cells to determine genotoxicity to the cells.
- Subchronic Toxicity Study - Sections of the stent were implanted in the subcutaneous tissue of the test subjects for 13 weeks. The subcutaneous tissue was then examined for systemic toxicity.
- ISO 2-, 12-, and 20-Week Muscle Implant Study - Sections of the stent were implanted in test subjects for 2, 12 and 20 weeks. At the end of that time the tissue around the sites was examined macroscopically and microscopically for irritation as compared to a control sample.

RESULTS:
The tests met the requirements as specified by ISO 10993.

CONCLUSION:
Based upon consideration of the overall results of this evaluation, the Inlay Optima® Double Pigtail Ureteral Stent meets the requirements for biocompatibility for mucosal contact greater than 30 days.

*Study performed by C. R. Bard, Inc.