July 21, 2011

Richard Dowdy
Egret Medical Products
2713 Industrial Lane
Garland, TX 75041

Re: User Experience with Performance of Egret Suction Catheter

Dear Sirs:

This is a report summarizing our experience using the Egret In-Line Suction Catheter. The respiratory therapists assigned to intubated patients receiving mechanical ventilation in our adult intensive care units evaluated the Egret In-Line Suction Catheter in 2008 to 2010.

Approximately 100 catheters were evaluated in use. Our staff was very pleased with the performance of the catheter. We found the design of the Egret catheter to be superior to the standard in-line catheters utilized at our facility. Some of the features that were commented on in a positive manner:

- Swivel connectors reduced twisting of the catheter tubing.
- Superior function of the suction control button.
- Superior function of the locking mechanism of the suction control button.
- Extended duration of use of the catheter.

Durability of the Egret catheter used for extended times was comparable to the standard catheter used at our facility that were changed out daily. We experienced only one instance of the sheath of the Egret catheter tearing but this was attributed to user-error actions.

In summary, our experience with using the Egret In-Line Suction Catheter was very positive.

Regards,

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Egret Medical Products Inc.

Extended Term™ In-line Endotracheal Suction Catheter w/BIOSAFE™

Use Test Summary

Protocol Number: **RT 2008-001**

Richard C. Dowdy – Study Sponsor

January 5, 2010

Background

As per Protocol RT 2008-001, clinicians who participated with Egret's clinical trial were asked to complete a questionnaire (see attached). In total, 90 questionnaires were completed and returned to the sponsor.

Results

	Not Acceptable	Same as Current	Improved
Use of Change-Out Label		62	28
Connection to Suction Tube		62	28
Suction Valve – Ease of Use		6	84
Gage and Feel of Sheath Material		48	42
Valve Locking Safety Feature		3	87
Ease of Connection to the Trach or ET Tube		53	37
Catheter Positioning and Ease of Manipulation		18	72
Communication\Visibility of Depth Markings		72	18
Use of Saline Ports		71	19
Tip Cleaning Process and Result		65	25
Product Flexibility to Patient Movement		14	76

Affect of Heat on Product Function		73	17
Perceived Weight of Product		36	54
Comfort to Patient		13	77
Did Sheath Remain Dry During Use?		67	23
Did End Cap Remain Secure?		79	11
Ease of Use After Disconnect		40	50

Additional Comments – No additional comments were reported on the questionnaire. The Clinical Investigator did share that in one incident they had an issue with the catheter being difficult to insert in the airway. This incident has been communicated to the design team and will be noted in the projects risk plan. No further observation or comments were provided to help explain this one incident.

Questionnaire

It should also be noted the Clinical Investigator determined the questionnaire did not need to address the patient being trached or intubated as originally identified in the use test protocol.

Summary

Products used for 1, 3, 5, 8, and 10 days have all been included in this summary. All results reported were rated equivalent or improved when compared to the device currently being used. There were five questions that had a significant number responding as an improvement (highlighted above).

Clinical Trial Report
Egret Extended Term™ Closed Suction System

INTRODUCTION

A Clinical Trial of the Egret Extended Term™ Closed Suction System ["Egret catheter"] was conducted at Medical City Hospital in Dallas, Texas, under IRB-approved Protocol #08.025, "Extended Use In-Line Endotracheal Suction Catheter w/BIOSAFE".

The purpose of the Trial was to:

1) determine whether the average aerobic bioburden levels on the surface of the catheters after use were statistically different between the Egret Catheter and the predicate device. The predicate device was the Kimberly-Clark Ballard Trach Care™ Closed Suction System ["Ballard catheter"] which is normally used at that hospital[1] ;
2) verify that there were no unexpected adverse events associated with the Egret catheter use;
3) obtain feedback from the respiratory care practitioners regarding comparative ease-of-use and design feature preferences between the Egret catheter and the Ballard catheter.

The Protocol included two studies. The first was a baseline study to determine the average aerobic bioburden level on the predicate Ballard catheter when changed out daily as per current Hospital policy[1] and the supplier's recommendation. The results of the baseline study were then used to determine the feasibility of, and the appropriate sample size for, the second study.

The second study was designed to compare the average aerobic bioburden levels on the Egret catheter and the Ballard catheter after clinical use. The Ballard catheter was changed out daily. The Egret catheter was used continuously for up to 10 days as the condition of the patient warranted.

Data analysis for both the baseline and the comparative study was performed by Egret Medical Products' consulting statistician, Morley Herbert, PhD, Biomedical Research & Biostatistician in the Department of Clinical Research at Medical City Dallas Hospital, using SAS 9.2 software (SAS Inc, Cary, NC).

BASELINE STUDY

The purpose of the baseline study was to determine the average aerobic bioburden level on the Ballard catheter after one-day use, and to use the resulting data to establish the feasibility of, and appropriate sample size for, performing the second, comparative study. Medical City Hospital typically has between 17-20 patients in its ICU ward at any one time. Baseline samples were taken from patients over a representative two day period, for a total of 26 samples.

Immediately after patient use, each catheter was individually placed in an ice pack bag and tied to prevent cross-contamination, and then placed in an ice chest for transportation to an independent laboratory, MicroChem Laboratory, Inc., Euless, Texas, for testing. Each catheter was received at MicroChem Laboratory within 24 hours after use in the patient.

MicroChem Laboratory then assayed each catheter using aseptic technique to measure the total number of aerobic bacteria per catheter tip. The first 6 cm of the catheter were cut as three 2 cm sections using sterile flamed scissors. The three 2 cm sections were placed into 10 ml of nutrient broth and were agitated on a vortex mixer for 30 seconds. A series of ten-fold dilutions was made, and measured portions of each dilution were transferred to sterile petri plates and mixed with molten nutrient agar. Plates were allowed to solidify and then incubated for ≥ 48 hours at 35 ± 2ºC. The colonies were counted and multiplied by the appropriate dilution factors to determine the number of colony forming units (CFU) of bacteria on and associated with the catheter tips.

The results[2] of the baseline study showed an average (± standard deviation) aerobic bioburden level of 1.84 (± 5.00) x 10^7 CFU/catheter tip. The experience gained during the baseline study indicated that the planned comparative study was feasible. The data from the baseline study was then used to determine an appropriate sample size for the comparative study.

COMPARATIVE STUDY

Determination of Sample Size

The purpose of the comparative study was to determine whether there was a statistical difference ($\alpha = 0.05$) in average bioburden levels for the Egret catheter when used continuously for up to 10 days, as compared to the predicate Ballard catheter when changed out daily. The consulting statistician initially determined that, based on the baseline study results, detecting a 20% difference in the average bioburden at 80% power and a confidence level of 95%, would require a sample size of 82 for both Egret and Ballard catheters. To account for lost samples, possible contamination or outliers, it was decided to use a sample size of 100 for both Egret and Ballard catheters. (See "Note" under "Results of t-Test Comparisons" below.)

Test Plan

The Egret and Ballard catheters were both Adult 14 Fr. models. The Egret catheters were used continuously for up to 10 days as the condition of the patient warranted. The Ballard catheters were changed out daily per the supplier's recommendation and current Medical City Hospital policy[1]. Immediately after patient use, the catheters bagged and transported to MicroChem Laboratory and were assayed for aerobic bioburden in a similar manner as had been done for the baseline study.

The Egret catheters were tested for bioburden levels after 1, 3, 5, 8, and 10 days of continuous use. The Protocol called for 20 Egret catheters to be tested at each of the 5 time periods. However, 21 Egret catheters were actually tested after 1 day of use, and 19 Egret catheters were tested after 8 days of use. Twenty Egret catheters were tested at each of the other time periods.

Twenty Ballard catheters were tested after 1 day of use at each of the 5 Egret catheter sampling points. The 20 Ballard catheters that were in use on day 1 of Egret catheter use were tested immediately following that single day of use. The 20 Ballard catheters that were in use on day 3 of Egret catheter use were tested immediately following that single day of use. The 20 Ballard catheters that were in use on day 5 of Egret catheter use were tested immediately following that single day of use. And similarly for days 8 and 10 of Egret catheter use.

This information is shown in Tables 1 and 2.

Table 1. Egret Adult 14 Fr. T-Piece Catheter.

Study Group	Number of days device was used	Number of patients assigned to Egret Catheter	Number of Egret Catheters used in Study
1	1	21	21
2	3	20	20
3	5	20	20
4	8	19	19
5	10	20	20
	TOTAL	**100**	**100**

Table 2. Ballard Adult 24 Fr. Elbow Catheter .

Study Group	Numbers of days device was used	Number of patients assigned to Ballard Catheter	Number of catheters required for study
1	1	20	20
2	1	20	60
3	1	20	100
4	1	20	160
5	1	20	200
	TOTAL	**100**	**540**

Daily change-out required the use of 540 Ballard catheters to treat 100 patients. Due to extended use, only 100 Egret catheters were required to treat 100 patients for the same time period.

Key Methodology

- Informed consent was obtained for each patient treated with the Egret catheter.
- Both Egret and Ballard catheters were used from the outset of patient intubation. No patients were used in the study who were already on a ventilator.
- Patients with confirmed Ventilator-associated Pneumonia (VAP) were excluded from this study.
- The Egret catheter was used as per hospital policy with the exception that change-out was not required daily.
- Caregivers were instructed on how the catheters were to be flushed and rinsed after suctioning. This was the standard hospital procedure, and was used to flush and rinse both the Egret and the Ballard catheters.
- The microbiological test laboratory was blind to how many days each Egret catheter had been used.

Results and Analysis

One hundred Ballard catheters and 100 Egret catheters were assayed for aerobic bioburden. The blinding-coded results reported by Microchem Laboratory[3] were then de-coded by the clinical Investigator and provided to the consulting statistician for analysis.

Because the Ballard catheters were all used for 1 day by manufacturer's design, it was decided to compare the Egret bacterial counts at each time period to the pooled data from the 1-day Ballard use. Data analysis was carried out using SAS 9.2 (SAS Inc, Cary, NC).

Standard t-tests were used to compare the bacterial counts of the Egret catheters from each time period to the bacterial counts of the pooled Ballard group, using a 95% confidence level. One Egret value from 3-day use (114×10^6) was deemed to be an outlier and was deleted, since it was more than 230 times the standard deviation for the 3-day use data.

The averages (± standard deviation) for aerobic bioburden on the catheters are shown as Colony Forming Units (CFU) per catheter tip:

Pooled Data

Ballard (100 samples) Mean ± std $(2.15 \pm 8.63) \times 10^6$
Egret (99 samples) Mean ± std $(0.55 \pm 3.68) \times 10^6$

Egret Catheter Data (based on days of use)

1 day (21 samples) Mean ± std $(7.91 \pm 27.35) \times 10^3$
3 day (19 samples) Mean ± std $(163.31 \pm 537.17) \times 10^3$
5 day (20 samples) Mean ± std $(114.70 \pm 266.16) \times 10^3$
8 day (19 samples) Mean ± std $(32.72 \pm 94.31) \times 10^3$
10 day (20 samples) Mean ± std $(2.42 \pm 8.05) \times 10^6$

Results of t-Test Comparisons

For each period of use (1 day, 3 day, 5 day, 8, 10 day), the average Egret catheter bioburden was compared to the pooled average 1-day-use Ballard catheter bioburden, using standard two-sample t-tests at $\alpha = 0.05$. The results are shown in Table 3.

Table 3 Results of t-Tests

Days of Egret Usage	Significant Difference? ($\alpha = 0.05$)	Lower Bioburden	p-value
Day 1 Egret vs Ballard	Yes	Egret	0.015
Day 3 Egret vs Ballard	Yes	Egret	0.025
Day 5 Egret vs Ballard	Yes	Egret	0.020
Day 8 Egret vs Ballard	Yes	Egret	0.016
Day 10 Egret vs Ballard	No	Same	0.897

Note: After the trial was completed, the consulting statistician informed Egret Medical Products that he had made an inadvertent error in calculating the desired sample size, and that the sample size should have been greater than he had originally determined.. However, the analysis of the trial results showed that the sample size of 100 each of Egret and Ballard catheters had been sufficient to demonstrate a significant difference in the average bioburden levels at the 95% confidence level, as shown in Table 3 above.

Adverse Events

There were no adverse events associated with use of the catheters during the trial.

Feedback from Respiratory Care Practitioners

Feedback Questionnaire

The Protocol for the clinical study included providing the respiratory care practitioners (RCP's) with a Use-Test Questionnaire to compare the functionality of the Egret and Ballard catheters and to record the RCP's preferences. The questionnaire included 17 features for which the RCP's were asked to rate the Egret catheter as either "not acceptable", "same as current [the Ballard catheter]", or "improved" as compared to the Ballard catheter.

Questionnaire Results

All of the RCP's rated the Egret catheter as either "same as current" or "improved" as compared to the Ballard catheter in all 17 categories. A significant number of RCP's rated the Egret catheter as an improvement compared to the Ballard catheter in the following five categories: suction valve ease of use; valve locking safety feature; catheter positioning and ease of manipulating; product flexibility to patient movement; comfort to patient.

Questionnaire Conclusions

The RCP users rated the Egret Extended Term™ Closed Suction System superior to the predicate device as regards several functionality and ease-of-use features.[4]

CLINICAL TRIAL CONCLUSIONS

1) the Egret Extended Term™ Closed Suction System may be safely used for up to 10 days of continuous use;

2) the Egret catheter had a lower aerobic bioburden level when used for up to 8 days of continuous use as compared to the aerobic bioburden level on the Ballard catheter after only 1 day of use

3) the Egret catheter had an equivalent aerobic bioburden level when used for 10 days of continuous use as compared to the aerobic bioburden level on the Ballard catheter after only 1 day of use.

4) the clinicians (RCP's) showed a strong preference for several of the design features of the Egret catheter as compared to the Ballard catheter.

Cited References

1. Medical City Dallas Hospital, Policies and Procedures, Policy No. RSCC12 – Endotracheal Suctioning
2. MicroChem Laboratory – Laboratory ID No. 080303-1, A Study to Measure the Total Aerobic Bacteria on Ballard Suction Catheters During 24 Hours Use with Respiratory Care Patients, March 19, 2008.
3. MicroChem Laboratory – Laboratory ID No. 080613-2, A Study to Measure the Total Aerobic Bacteria on Egret Suction Catheters After Extended Use in Respiratory Care Patients as Compared to a Non-Treated Control Suction Catheter After 24 Hours Use", November 18, 2009.
4. Egret Medical Products, Use Test Summary, January 5, 2010