SterilMed Technical Addendum

Response to "Assessment of Reprocessed Arthroscopic Shaver Blades" in the Journal of Arthroscopic & Related Surgery October 2006

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Summary

Objective

Analyze and respond to Smith & Nephew sponsored Journal of Arthroscopic & Related Surgery article titled "Assessment of Reprocessed Arthroscopic Shaver Blades"

Results

This study should not be used to make any conclusion about reprocessed shaver blades for the following reasons:

1. The samples Smith & Nephew provided should not have been used in the study because they:
   a. were not representative of those reprocessed using an FDA compliant cleaning process
   b. would not have met SterilMed quality control parameters
2. Regulatory requirements have increased dramatically since the samples were collected and the study concluded.
3. The study can make no observations regarding cleaning without noting surface area and comparing the results to FDA-accepted AAMI cleanliness criteria.

Conclusion

The Smith & Nephew sponsored journal article is a combination of questionable science and misinformation. It is a clear attempt to distort the facts that reprocessing using an FDA-compliant process is proven to be safe and effective.

SterilMed has safely reprocessed arthroscopic shavers under 510(k) K012536 since 2001.

Background:

Smith & Nephew, a major manufacturer of orthopedic medical devices including many devices labeled for "single use," funded a study of reprocessed shavers published in the Journal of Arthroscopic & Related Surgery in October, 2006. The stated purpose of the study was to evaluate the cleanliness and quality of reprocessed shaver blades. It purports to have discovered problems with reprocessed devices. This is not surprising given that the study was underwritten by a company that gains financially when devices are not reprocessed. In addition, these studies were conducted using non-FDA compliant reprocessed devices. Consequently, they do not represent a valid evaluation of single-use-device reprocessing as it is currently conducted and regulated.

Smith & Nephew funded a similar study several years ago and sought to have it published in the same journal in early 2004. Because of concerns regarding the size of the sample studied, the origin of the devices used in the study, and the chain of custody of the devices from the time they left the possession of the reprocessor to the time that the study authors examined them, the authors voluntarily withdrew this study from consideration for publication in the journal.

Now, two years later, a remarkably similar study, with three of the five same authors has appeared. Like the original study, this version has similar flaws that negate its conclusions. The key errors are:

1. Samples were not cleaned in accordance with FDA guidance

No information is provided on the companies who supposedly reprocessed the devices. There is little doubt that some of the samples were not cleaned following FDA guidelines. For example, the first set of devices exhibits an average protein value of 51.75µg/device for devices which had any detectable protein, while the unreprocessed control had a protein residue of 53.8µg/device, suggesting that the reprocessed devices which exhibited detectable protein residue might not have been cleaned at all. Conversely, the majority of the set 1 reprocessed devices (12 of 16) had no detectable protein, which is the same as the new shaver.

The samples Smith & Nephew provided were not representative of those reprocessed using an FDA validated cleaning process and should not have been used in the study.

2. Samples were not refurbished in accordance with FDA guidance

Unlike Smith & Nephew's new shavers, each reprocessed device from SterilMed is visually inspected for sharpness before shipment. Refurbishment includes identical matching of the original blade profile through computer numeric control (CNC) sharpening techniques. (See SterilMed Technical Bulletin - SM103 - Reprocessed Orthopedic Bits, Saw Blades and Shavers.) FDA compliant processes ensures performance equivalent to new devices.

The samples Smith & Nephew provided would not have met SterilMed quality control parameters and should not have been used in the study.

3. The FDA made sweeping regulatory changes since the study was completed

No information is provided on when the shavers were reprocessed. Smith & Nephew attempted to get the study published in early 2004 so the samples would have been collected before then. In fact, the authors note they could not determine how many times the blades had been reprocessed. Since devices had to be "clearly marked to

identify the number of reprocessing uses" as required by the FDA since 2001, it seems likely that the samples were processed over five (5) years ago.

In 2002, the FDA required submission of reprocessing protocols. In 2004, subsequent to promulgation of MDUFMA regulations, the FDA strengthened validation criteria for substantially equivalency. Subsequently, only three (3) third-party reprocessing firms (of the estimated 20) survived the FDA scrutiny and the business conditions of meeting regulatory conditions.

SterilMed has used FDA compliant validated processes under 510(k) K012536 since 2001.

Regulatory requirements have increased dramatically since the samples were collected and the study concluded.

4. The cleanliness criteria was incorrect

With regard to cleaning requirements, the FDA has accepted AAMI Technical Bulletin (TIR-30) recommendations for reusable devices. Contaminant values are reported in µg/device whereas both TIR-30 and the FDA require that benchmark values be given in µg/cm^2 to allow comparison of different devices, methods and assays. For example, TIR-30 offers a protein acceptance criterion of 6.4µg/cm^2 for reusable medical devices. Given that King et al. report protein averages of 7.0µg/device (set 2 in the manuscript), unless the device has a surface area of 1 cm^2 or less these protein values are well within the TIR-30 and FDA acceptance criteria for reusable medical devices.

The study also infers that any level of protein detection posses a risk of infection. There is no evidence to support this hypothesis. To the contrary, reusable devices have been proven safe when cleaned by hospitals in accordance with AAMI detectable protein guidelines.

The study can make no observations regarding cleaning without noting surface area and comparing the results to FDA cleanliness criteria.

Conclusions

The Smith & Nephew sponsored journal article is a combination of questionable science and misinformation. It is a clear attempt to distort the facts that reprocessing using an FDA-compliant, validated process is proven to be safe and effective. We have reached three conclusions:

1. The samples Smith & Nephew provided should not have been used in the study because they:
   a. were not representative of those reprocessed using an FDA validated cleaning process
   b. would not have met SterilMed quality control parameters
2. Regulatory requirements have increased dramatically since the samples were collected and the study concluded.
3. The study can make no observations regarding cleaning without noting surface area and comparing the results to FDA-accepted AAMI cleanliness criteria.

References:

[1] King J, Pink M, Jobe C. Assessment of Reprocessed Arthroscopic Shaver Blades. Arthroscopy: The Journal of Arthroscopic & Related Surgery, Oct 2006;22(10):1046-1052.

[2] Lester B. Technical Bulletin, Reprocessed Orthopedic Bits, Saw Blades and Shavers, Summary of Cleaning and Functional Test Results. SterilMed, Inc. 2006;SM103.

About the Author

Dr. Bruce R. Lester has more than 25 years experience in biological and biomedical research working in both industry and academic environments. He obtained his Ph.D. at Purdue University, completed a post doctoral fellowship at Baylor College of Medicine, worked at Smith Kline Pharmaceutical and has served on the faculty of the University of Minnesota for 13 years. Dr. Lester is presently Chief Science Officer at SterilMed, Inc.