



EDCO FORUM[®]

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 14 NUMBER 52

OCTOBER 2007

REPRINT

DISPOSABLE CANNULAS OFFER PHYSICIANS AND PATIENTS GREATER PEACE-OF-MIND

Challenges associated with sterilizing cannulas and other surgical instruments introduce additional risks into liposuction and fat transfer procedures for many reasons:

- **Design of cannula.** Thorough cleaning of reusable cannulas is often difficult because they are closed at one end and have a narrow shaft. Five-years ago, a California cosmetic surgery practice reported higher than normal infection rates because of improper cleaning of liposuction equipment.¹ Inadequate cleansing of instruments may increase the risk of cross-contamination of hepatitis and HIV.²

- **Limited effectiveness.** Even meticulous autoclaving does not kill all organisms. For example, prions, the causal agent of Bovine Spongiform Encephalopathy (Mad Cow Disease) and Creutzfeldt-Jakob disease, are resistant to standard disinfection and sterilization protocols—and cases of acquired prion disease have been associated with inadequately cleaned instruments.³

- **Corrosion of instruments.** Internal corrosion of the cannula may damage fat cells and tissues, reducing procedure quality and extending patient recovery times.² Subtle ridges in reusable cannulas that have been used beyond a normal “lifespan” may trap tissues, and sterilization cannot guarantee complete removal of this treatise.²

- **Short lifespan.** A double-blind study conducted at the University of California San Diego compared the inner surface of disposable cannulas with that of reusable cannulas. Nitrogen-hydrogen bonds (indicative of the presence of human tissue) were found on cleaned and autoclaved reusable cannulas. This suggests a potential risk of transferring protein-residue material from one patient to another when using reusable cannulas that may not be properly cleaned or have been used beyond an acceptable time period.⁴

- **Public health concerns.** Medical devices with lumens and long narrow shafts (e.g., cannulas) present challenges for cleaning, disinfecting and sterilizing as it is impossible to access or visualize the entire surface area. Decommissioning difficult-to-clean medical devices—and substituting disposable devices—could assist in reducing associated public health risks.⁵



Cost-efficient, disposable cannulas reduce the need to invest in reusable equipment.

Europe Revises Sterilization Standards

An interesting issue influencing the choice between disposable and reusable cannulas is developing in Europe. In 2007, standards for the three primary methods of sterilizing medical devices—ethylene oxide, radiation and moist heat—were revised (according to *Sterilization of Health Care Products, Ethylene Oxide/Radiation/Moist Heat, Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices*⁶). The revised standards are available to all European countries, and are to be adopted as their national standards.

The updated moist heat standards keep both the new and older standards in force for the next three years. With respect to moist heat sterilization (e.g. autoclaving), the revised standards may make continued use of reusable cannulas more complex by adding administrative and documentation burdens for plastic and cosmetic surgeons and their staff. Use of disposable cannulas is an attractive alternative for reducing these expensive and time-consuming burdens.

Tulip BioMed, Inc., the leader in the design, production, and sale of single-use disposable cannulas and other tools used in the plastic and cosmetic surgery fields, is currently in the process of securing regulatory approval to market and sell its FDA-approved products outside of the United States, and expects to have such approval within the fourth quarter of 2007.

Tulip BioMed's Disposable Cannulas

- Highly successful for fat transfer procedures, whose popularity is on the rise because fat lasts longer than artificial fillers
- Features SuperLuer Lok™, single-use, sterile, devices
- Attaches securely to syringes
- Includes hydrophilic coating—cell-friendly material that helps maintain integrity of both skin and fat used for soft tissue fillers
- Provides clean, slick surface—offering both physicians and patients peace-of-mind during liposuction and fat transfer procedures, at an insignificant cost
- Offers flexible tip styles
- Provides a color-coded size identification system
- Offers direct-from-manufacturer purchasing

Benefits of Disposable Cannulas

Tulip BioMed's single-use disposable cannulas reduce the risk of cross contamination, eliminate the possibility of infection due to accidental instrument contamination, and help to decrease liability concerns for physicians. Both the design and coated surface of Tulip BioMed's cannulas also offer significant benefits to patients.⁷

Dr. Mark J. Glasgold, M.D., F.A.C.S., clinical assistant professor at UMDNJ-Robert Wood Johnson Medical School, notes that "physicians may as well use disposables because of the difficulty cleaning reusables—disposables offer a lower risk of clogging and enhanced patient safety." Dr. Glasgold continues, "There is a dramatic difference in recovery time with the 0.90mm cannula—patients experience significantly less bruising and one-week less recovery time."

Samuel M. Lam, M.D., F.A.C.S. (co-author with Dr. Glasgold of *Complemen-*

tary Fat Grafting, as well as author of three textbooks—including the only cosmetic surgery textbook of the Asian face in the English language), finds disposables valuable for use with artificial fillers. Dr. Lam says, "disposable cannulas are advantageous given the quickness of the procedure." Dr. Lam (who receives no royalties or compensation from Tulip) worked with Tulip to create a disposable cannula for use with artificial fillers. He notes that "the sterility of disposables is valuable because of the nature of the fillers and the tendency of residual product to build up in reusables—requiring both significant time and effort to clean out."

Unique Tulip BioMed Advantages—Size and Control


Oscar M. Ramirez, M.D., F.A.C.S., Assistant Clinical Professor at the Johns Hopkins University School of Medicine and University of Maryland School of Medicine, uses Tulip BioMed disposable cannulas "because they offer small, 0.90mm disposable cannulas." Dr. Ramirez noted that he "uses the 0.90mm disposable for fat grafting and injections of local anesthetic, particularly around the eyelids, because it reduces trauma to the vessels and lessens bruising."

The coating material of Tulip Disposable cannulas, continues Dr. Ramirez, "allows the cannula to glide very easily through tissue, the sensation is the same as working with a needle." Dr. Glasgold also selects Tulip Disposables because, "the cell-friendly coating technology gives superb control—and this smooth injection control is critical in terms of avoiding complications." The hydrogel surface absorbs fluid resulting in less cell trauma and enhances the viability of the cells for reinjection. Disposable cannulas offer increased procedure quality and decreased post-surgical bruising—translating to more predictable surgical outcomes and better patient satisfaction.

Disposable cannulas also reduce the need to invest in reusable equipment, minimizing overhead associated with cleaning and sterilization.

An Added-Benefit—Tulip BioMed's SuperLuer Lok

Leveraging a strong history of developing groundbreaking technologies of innovator John Johnson, Tulip BioMed is the first to offer disposable cannulas with the SuperLuer Lok technology. Dr. Ramirez says the SuperLuer Lok "is very secure and prevents loss of suction at the interface of the syringe and cannula, especially when pressure is applied." Tulip's SuperLuer Lok:

- Offers enhanced strength and rigidity at the syringe and cannula connection point
- Eliminates leaking
- Creates a static vacuum
- Allows for more aggressive manipulation during procedures. 

Tulip BioMed, Inc.
tulipdisposable.com

TULIP
BioMed™

- Disposable micro cannulas
- Disposable 60cc macro cannulas (typically used for liposuction)
- Disposable Johnnie Lok™ (designed to lock and hold the plunger of a 10/12cc and 20cc syringe under vacuum)
- Disposable Luer-to-Luer transfer device

To Learn More

To learn more, visit the company's Web site at www.tulipdisposable.com, call 1-800-978-8547, or email to info@tulipdisposable.com. Promotional discounts are available.

References:

1. Meyers, H., B. Brown-Elliott, D. Moore, J. Curry, C. Truong, Y. Zhang, and R. Wallace, Jr. An Outbreak of Mycobacterium chelonae Infection Following Liposuction. *Clinical Infectious Diseases*. 2002;34:1500-1507 Accessed online at www.journals.uchicago.edu/cgi-bin/resolve?CID011270.
2. Improving Liposuction and Fat Transfer Procedures: The Case for Disposable Cannulas. Cell Bio-Systems White Paper, February 1, 2006. Accessed online at www.tulipdisposable.com.
3. Ena, J. Prions: who should worry about them? *Arch Med Res*. 2005 Nov-Dec;36(6):622-7.
4. Residue remains in reusable cannulas despite cleaning. *Cosmetic Surgery Times E-News*. Jun 12, 2007 Accessed online at www.cosmeticsurgerytimes.com/cosmeticsurgerytimes/article/articleDetail.jsp?id=432212.
5. "Reducing Public Health Risks associated with Reusable Medical Devices" pages 7-8. National Coordinating Committee on Therapeutic Goods (Australia) May 2004. Accessed at www.tga.gov.au.
6. Hoxey, E., Strañ, P., Harries, J. and Kirk, B. Regulations and Standards. Revised Standards for Sterilisation: The Changes. *Medical Device Technology*, March/April 2007. Accessed online at www.devicelink.com/mdt/archive/07/03/010.html.
7. Tulip BioMed believes that there is and will continue to be a need for reusable cannulas, provided that such cannulas are replaced on a more frequent basis.