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Dermal Filler Fact Sheet

There is a large, growing demand among American consumers for minimally invasive cosmetic procedures. Recent statistics released by the American Society for Aesthetic Plastic Surgery (ASAPS)¹ show enormous consumer demand that created a dermal filler market that is estimated to be worth \$80 million.²

Of the 11.8 million cosmetic procedures performed in the United States in 2004, 9.7 million or 82 percent were non-surgical in nature¹

The 35- to 50-year old age group is the fastest-growing demographic in the developed world and accounted for 45 percent of the 11.8 million cosmetic procedures performed in the U.S. in 2004²

More than 1.8 million dermal filler treatments were administered in 2004³

In 2004, collagen injections were the sixth most common aesthetic procedure in the U.S. with more than 785,000 treatments 31.5 percent used bovine-derived collagen products and 68.5 percent used human-derived collagen products¹

With the introduction of the hyaluronic acid-based products into the U.S., the market is projected to grow to about \$175 million by 2007⁴

Hyaluronic acid-based fillers, such as Inamed's Captique® and Hylaform®, surpassed collagen to become the fifth most common aesthetic procedure in the U.S. with 880,000 treatments last year¹

BOTOX® Cosmetic (botulinum toxin type A) and Dermal Fillers

Allergan's BOTOX® Cosmetic, which is considered by the American Society for Dermatologic Surgery (ASDS) as the gold standard for treating glabellar lines (the dynamic vertical frown lines between the brows), is often used in combination with dermal fillers. BOTOX® Cosmetic works to relax the facial muscles that cause glabellar lines by blocking nerve impulses that trigger wrinkle-causing muscle contractions, creating a smoothed and improved appearance between the brows.

Dermal fillers replace tissue volume below the surface of the skin to alleviate the appearance of facial lines at rest. Unlike glabellar lines, these lines usually appear in the lower portion of the face.

Dermal Fillers Overview

Over time, collagen and hyaluronic acid in the skin diminish causing the skin to lose structure and volume, so wrinkles appear. Increasingly, physicians are using collagen and hyaluronic acid-based dermal fillers in combination to temporarily replace this loss, smoothing away unwanted lines and wrinkles.⁵

Dermal fillers are made from a variety of natural, man-made or synthetic materials that have been developed for injection into the skin. Fillers come in different thicknesses, and in general, the thicker the product, the deeper it is injected into the dermal layer of the skin to add volume and smooth lines and wrinkles. Dermal fillers are not new. Doctors as early as the 1890s could take fat from patients' arms and inject it below the surface of the skin as filler. By the mid 1900s, doctors were using paraffin and then silicone, until the 1980s when American scientists discovered a type of collagen that occurs naturally in cows' skin and was safe in humans. In 1981, collagen—a protein that provides skin with structural support—was the first filler approved by the U.S. Food and Drug Administration (FDA) for soft-tissue filling by injection.⁶

Today, there are human-derived collagen products on the market that are more commonly used as dermal fillers, such as those made from a highly purified form of hyaluronic acid. Hyaluronic acid is a natural sugar found in living cells that attracts and binds water, hydrating the skin and giving it volume. Most treatments do not require a skin test, can

be carried out when wanted and show immediate results. Treatment and recovery time is typically less than one hour.⁷

Aesthetic Use

Dermal fillers are most often used to enhance appearance. They have been administered for years to increase the size and volume of women's lips, and this remains the most popular use. Treatments are effective in both men and women to fill out lines around the lips, the lines from the nose to the corners of the mouth (nasolabial lines), smile lines, crow's feet and forehead wrinkles. Thicker fillers also can be used to add volume to sunken cheeks and weak chins, reshape the tip of the nose, fill out deeper scars or even treat more significant non-facial skin defects.

Therapeutic Use

Although more commonly used for aesthetic purposes, dermal fillers also are administered therapeutically. Hyaluronic acid has been used in cataract operations and for injection into arthritic joints to aid movement. Areas in which hyaluronic acid and dermal fillers are used include:

Drug delivery

Ophthalmology

Orthopedics

Rheumatology

Urology

General wound healing

Human vocal cord paralysis

Adhesion prevention

Inadequate or damaged tissue caused by surgery, injury, or disease

Key Inamed Dermal Filler Products

Captique®

Approved by the FDA in December 2004 for the correction of moderate to severe facial wrinkles, Captique is the newest non-animal stabilized hyaluronic acid dermal filler.

Hylaform®, Hylaform Plus® and Hylaform Fineline®

Approved by FDA in April 2004 for the correction of moderate to severe facial lines and wrinkles, Hylaform replenishes the skin's lost hyaluronic acid, restoring skin volume.

Juvederm® Dermal Filler Product Line

The Juvederm® dermal filler product line is a range of products based on non-animal, crossed linked, homogenous gel hyaluronic acid-based products. Juvederm® is available in several ex-U.S. markets, including the EU where the product is marketed by LEA Derm under the brand name Hydrafil®. Juvederm® is currently under clinical development in the U.S.

CosmoDerm® and CosmoPlast®

Approved by the FDA in March 2003, these are the first FDA-approved fillers that do not require a skin test before treatment and the only ones on the U.S. market with anesthetic and the ability to deliver immediate results.

CosmoDerm® and CosmoPlast® replenish skin's lost collagen.

Zyderm® and Zyplast®

Introduced 18 years ago, Zyderm® and Zyplast® injectable collagen implants have set the standard in filler materials for smoothing facial lines, wrinkles and scars and in providing lip border definition. Today, more than one million people worldwide have been treated with Zyderm® or Zyplast® collagen implants.

Forward-Looking Statements

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Information below). Risks and uncertainties relating to the proposed transaction include: that required regulatory approvals will not be obtained in a timely manner, if at all; that the anticipated benefits and synergies of the transaction will not be realized; that the integration of Inamed's operations with Allergan will be materially delayed or will be more costly or difficult than expected; and that the proposed transaction will not be consummated. These risks and uncertainties could cause actual results to differ materially from those expressed in or implied by the forward-looking statements, and therefore should be carefully considered.

Additional Information

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¹ American Society for Aesthetic Plastic Surgery. Cosmetic Surgery National Data Bank Statistics. Available at: <http://www.surgery.org/download/2004-stats.pdf> Accessed on October 28, 2005.

² JP Morgan.

³ American Society for Aesthetic Plastic Surgery. Quick Facts 2004. Cosmetic Surgery National Data Bank Statistics. Available at: <http://www.surgery.org/press/procedurefacts-asqf.php> Accessed on October 28, 2005.

⁴ Medtech Insight LLC.

⁵ Inamed Corporation. Facial Aesthetics – US Patients: Product Information. Available at: <http://www.inamed.com/products/facial/us/patient/patient.html>. Accessed October 28, 2005.

⁶ ConsultingRoom.com.
http://consultingroom.com/Aesthetics/Treatment/Treatment_Details.asp?Treatment=21

⁷ Inamed Corporation. Facial Aesthetics – US Patients: Product Information. Available at: <http://www.inamed.com/products/facial/us/patient/patient.html>. Accessed October 28, 2005.

Breast Aesthetics Product Fact Sheet

According to the American Society of Plastic Surgeons (ASPS), more than 325,000 breast implant procedures were completed in 2004 – 20 percent for reconstructive surgery following mastectomy and 80 percent for breast augmentation. In fact, breast augmentation was the second most commonly performed cosmetic surgical procedure after liposuction last year.¹

Saline and Silicone Breast Implants Overview

A breast implant is a prosthesis used in cosmetic surgery to reconstruct or enhance the size and shape of a woman's breasts.²

For breast reconstruction, Inamed Corporation's reconstruction implants are designed with tissue expanders and matching saline-filled or silicone gel-filled implants to provide patients with the choices necessary to attain an aesthetic breast shape. Many of the reconstructive products have a unique textured surface (BIOCELL® and BIOSPAN®) designed to reduce the chance of capsular contracture (hardening of the scar tissue around the implant) and promote tissue adherence, which may help to hold the implant in place. These implants are available in six styles.³

For breast augmentation, Inamed has five styles of implants also designed with tissue expanders and matching saline-filled implants to provide patients with the choices necessary to attain an aesthetic breast shape, including the uniquely textured BIOCELL® surface.⁴

Implants for Breast Reconstruction

According to ASPS, reconstruction of a breast that has been removed due to cancer or other diseases is one of the most rewarding surgical procedures available today. New medical techniques and devices have made it possible for surgeons to create a breast that can come close in form and appearance to matching a natural breast.⁵

Frequently, reconstruction is possible immediately following mastectomy, so the patient wakes up from surgery with a breast mound already in place.

Overall, there has been a 40 percent increase in reconstructive procedures since 1992. For breast reconstruction alone, there were twice as many procedures conducted in 2004 than in 1992.⁶

Implants for Breast Augmentation

Breast implants are most often used to enhance appearance. Advances in breast implant technology and surgical technique are making breast augmentation a popular option among women of all ages.

In 2004, more than 264,000 breast augmentation procedures were performed.¹

From 2000 to 2004, patients choosing breast augmentation increased 24 percent.⁷

Safety and Efficacy

The new generations of saline and silicone implants have undergone rigorous safety testing, and are subject to strict U.S. Food and Drug Administration (FDA) regulatory standards. Years of experience with this operation has demonstrated highly satisfactory results for most patients considered suitable candidates for the surgery.

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- ¹ American Society of Plastic Surgeons. 2000/2002/2003/2004 National Plastic Surgery Statistics Cosmetic and Reconstructive Procedure Trends. Available at: http://www.plasticsurgery.org/public_education/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=16158. Accessed October 28, 2005.
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- ⁷ American Society of Plastic Surgeons. 2004 Quick Facts. Cosmetic and Reconstructive Plastic Surgery Trends. Available at: http://www.plasticsurgery.org/public_education/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=16144. Accessed October 28, 2005.

Obesity Intervention Fact Sheet

In the United States, an estimated 97 million adults are overweight or obese that is 55 percent of the American adult population. Despite growing obesity awareness, obesity is the second leading preventable cause of death and is today considered the most prevalent epidemic in the U.S. and a public health crisis throughout the world.¹ About 120,000 bariatric (obesity) operations were performed last year, triple the number performed just two years ago, or a 500 percent increase in number of bariatric surgeries performed annually since 1992. Industry estimates are that there will be more than 200,000 bariatric surgeries performed in the U.S. by 2005.²

BioEnterics® LAP-BAND® System Overview

Approved by the Food and Drug Administration (FDA) in June 2001, Inamed Corporation's BioEnterics® LAP-BAND® System (LAP-BAND®) is a market-leading, minimally invasive surgical approach to reduce the health risks of obesity.³ LAP-BAND® (laparoscopic adjustable gastric band) is the second-most-common bariatric procedure in the U.S., and the leading bariatric procedure worldwide, having been implanted in more than 100,000 patients. LAP-BAND® is less invasive than other obesity surgeries, such as gastric bypass or stomach stapling, and does not disrupt the way the body absorbs nutrients. It also is the only adjustable and reversible bariatric procedure, and is more cost-effective than gastric bypass or laparoscopic bypass surgery.⁴ In fact, gastric bypass is nearly twice the average cost of a LAP-BAND® procedure.⁵

The LAP-BAND® System, used primarily by surgeons specialized in obesity and other GI related disorders, would anchor the portfolio alongside the planned development of Allergan's BOTOX® (botulinum toxin type A) as a potentially minimally invasive treatment for gastroparesis and Allergan's proton pump inhibitor pro-drug for the potential treatment of gastrointestinal heartburn.

How the LAP-BAND® System Works³

The LAP-BAND® System is a unique and comprehensive quality system approach that works by inducing weight loss by reducing the capacity of the stomach, which restricts the amount of food that a person can consume.

During the procedure, surgeons usually use laparoscopic techniques (using small incisions and long-shafted instruments rather than a large incision), to implant an inflatable silicone band into the patient's abdomen.

The band is fastened around the upper stomach to create a new, tiny stomach pouch that limits and controls the amount of food one can eat. It also creates a small outlet that slows the emptying process into the stomach and the intestines.

As a result, patients experience an earlier sensation of fullness and are satisfied with smaller amounts of food. This, in turn, results in weight loss.

LAP-BAND® System Safety and Efficacy³

The LAP-BAND® System procedure is considered the least traumatic of all weight loss surgeries since there is no cutting, stapling or stomach rerouting involved. The laparoscopic approach to the surgery also offers the advantages of reduced post-operative pain, a shortened hospital stay and quicker recovery. If for any reason the LAP-BAND® System needs to be removed, the stomach generally returns to its original form.

The BioEnterics® IntraGastric Balloon (BIB®) System⁶

Inamed's BioEnterics® IntraGastric Balloon (BIB®) System is a non-surgical, non-pharmaceutical alternative for the treatment of obesity. The BIB® System is designed to provide short-term weight loss therapy to reduce health risks related to obesity or risks prior to vital surgery, or as part of a supervised weight loss program.

Endoscopically placed and inflated with saline, the BIB® System balloon (made of durable, elastic, high-quality silicone) partially fills the stomach to induce the feeling of fullness and support patients in reducing food intake and adopting new dietary habits. It is used in conjunction with a supervised diet and behavior modification program to help maintain weight loss over time after removal of the device, which can also be done endoscopically.

The BIB® System is available in several European countries; it is not currently available in the U.S.

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- ¹ Inamed Corporation. Obesity solutions – US Patients. Available at: <http://www.inamed.com/products/obesity/us/patient/patient.html>. Accessed October 28, 2005.
- ² The BBI Newsletter, July 1, 2004.
- ³ Inamed Corporation. Obesity solutions – US Patients. Available at: <http://www.inamed.com/products/obesity/us/patient/lapband/prodinfo.html>. Accessed October 28, 2005.
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- ⁵ Morgan Stanley report, 10/21/05.
- ⁶ Inamed Corporation. Obesity solutions – UK Patients. Available at: <http://www.inamed.com/products/obesity/uk/patient/patient.html#lapband>. Accessed October 28, 2005.

