

Directions for Use

INAMED

Silicone-Filled

Breast Implants



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INTRODUCTION

DIRECTIONS TO THE SURGEON

This document contains information that is essential to the patient consultation process. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with the use of this device.

The information supplied in this Directions for Use document is intended to provide an overview of essential information about INAMED Silicone-Filled Breast Implants, including the indications for use, contraindications, warnings, precautions, complications and a summary of clinical study results.

Patient Counseling Information

Sections of this Directions for Use document indicated by “Patient Counseling Information” contain points that the physician should review when counseling the patient about INAMED’S silicone-filled breast implants and breast implant surgery.

Physician Education

INAMED offers a physician education program via the INAMED Academy to educate physicians on issues relevant to INAMED’s breast implants. The primary goals of the INAMED Academy are to convey important information to physicians from INAMED’s multicenter clinical studies and implant retrieval analyses, and to ensure that physicians are equipped with the most current clinical outcome and risk information to provide to their patients. Please contact your local INAMED Aesthetics Sales Representative or the INAMED Customer Care Department for further information on the INAMED Academy and other INAMED physician education initiatives.

INFORMATION TO BE DISCUSSED WITH THE PATIENT

WARNINGS, PRECAUTIONS, ADVERSE EVENTS

Patient Counseling Information

Breast implant surgery is known to provide satisfaction to patients, HOWEVER, as with any surgical procedure, it is NOT without risks. Breast implantation is an elective procedure, and the patient must be well counseled and understand the risk/benefit relationship.

Each patient should receive INAMED’s *Important Information for Women About Breast Augmentation/Reconstruction with INAMED Silicone-Filled Breast Implants* included in the **Patient Planner**, during her initial visit/consultation. The surgeon or a designated patient counselor should

instruct the patient to read the patient information carefully and also discuss with the patient the warnings, precautions, and complications listed in this Directions for Use document. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation. Patients should understand that breast implant surgery can cause irreversible changes to the breast.

INFORMED CONSENT

Patient Counseling Information

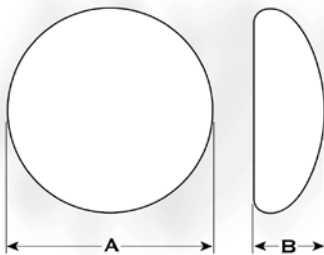
Before making the decision to proceed with surgery the patient should be allowed sufficient time to read and adequately understand the important patient information in INAMED's **Patient Planner** (patient decision-making aid) on the risks, follow-up recommendations, and benefits associated with silicone gel-filled breast implant surgery.

In order to document a successful informed consent process the Patient Planner also includes an *Acceptance of Risk and Consent to Surgery* document that should be signed by both the patient and the surgeon and then retained in the patient's file.

DEVICE DESCRIPTION

INAMED Silicone-Filled Breast Implants are constructed with barrier shell technology resulting in a low diffusion silicone elastomer shell and are filled with a soft, cohesive silicone gel. All styles are a single “lumen” round design and consist of a shell, a patch, and silicone gel fill. INAMED Silicone-Filled Breast Implants are dry heat sterilized and are available in both smooth and BIOCELL® textured surfaces.

Style Number	Breast Implant Description	Size Range
Style 10	Smooth shell surface, moderate profile	120cc – 800cc
Style 15	Smooth shell surface, mid-range profile	155cc – 752cc
Style 20	Smooth shell surface, high profile	120cc – 800cc
Style 40	Smooth shell surface, moderate profile	80cc – 560cc
Style 45	Smooth shell surface, full profile	120cc – 800cc
Style 110	BIOCELL® Textured shell surface, moderate profile	90cc – 510cc
Style 115	BIOCELL® Textured shell surface, mid-range profile	150cc – 716cc
Style 120	BIOCELL® Textured shell surface, high profile	180cc – 650cc



A = Width; B = Projection
Round Breast Implant

INDICATIONS

- Breast Augmentation - A woman must be at least 22 years old for breast augmentation.
- Breast Reconstruction
- Revision of previous breast augmentation or reconstruction to correct or improve the result of the previous surgery

CONTRAINDICATIONS

Patient Groups in which the product is contraindicated:

- Women with existing malignant or pre-malignant tumors of the breast without adequate treatment
- Women with an active infection anywhere in the body
- Women who are currently pregnant or nursing

WARNINGS

Surgical Practices in which product use is contraindicated due to potential for compromise of product integrity:

- **Alteration:** Do not alter the implant.
- **Stacking of implants:** Do not place more than one implant per breast.
- **Reuse:** Single use only. Do not reuse explanted implants.
- **Closed Capsulotomy:** Do not treat capsular contracture by forceful external compression, which will likely result in implant damage, rupture, folds and/or hematoma.
- **Periumbilical approach:** do not use the periumbilical approach for placement of the implant

AVOID DAMAGE DURING SURGERY

- **Care should be taken to avoid the use of excessive force and to minimize handling of the implant during surgical insertion.**

Data accumulated from INAMED's retrieval study analyses of explanted ruptured silicone gel-filled breast implants, observations of surgeries, and a review of the published literature, indicate that forcing an implant through too small an opening may result in localized weakening of the breast implant shell potentially leading to shell damage and possible implant rupture.

- **Care should be taken when using surgical instruments in proximity with the breast implant, including scalpel, sutures, and dissection instrumentation.**

Silicone-filled breast implants are prone to unintended instrument trauma during implantation or during explantation (Brandon et al. 2001, Young and Watson 2001). Failure can result from damage by scalpels, suture needles, hypodermic needles, hemostats, and Adson forceps, and has been observed in explanted device shells using scanning electron microscopy (Brandon et al. 2001). INAMED's analyses (retrieval study) of explanted devices have identified unintended surgical instrument damage as one potential cause of implant rupture.

- **Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant.**

Re-positioning of the implant during subsequent procedures should be carefully evaluated by the medical team and care taken to avoid contamination of the implant. Use of excessive force during any subsequent procedure can contribute to localized weakening of the breast implant shell potentially leading to decreased device performance.

- **Do not contact the implant with disposable, capacitor-type cautery devices.**
- **Do not insert or attempt to repair a damaged prosthesis.**

SINGLE USE DEVICES

Breast implants are single use devices only. Do not resterilize or reuse.

MICROWAVE DIATHERMY

The use of microwave diathermy in patients with breast implants is not recommended, as it has been reported to cause tissue necrosis, skin erosion, and extrusion of the implant.

PRECAUTIONS

SPECIFIC POPULATIONS

Safety and Effectiveness have not been established in patients with the following:

- Autoimmune diseases (for example, lupus and scleroderma).
- A compromised immune system (for example, currently receiving immunosuppressive therapy).
- Conditions or medications that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Radiation to the breast following implantation.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Patients should be assessed for any history of mental health disorders and should be referred to a mental health professional for further follow up and treatment if necessary. Patients with a diagnosis of depression or other mental health disorder should not undergo surgery until these conditions resolve.

MAMMOGRAPHY

Patient Counseling Information

With breast implants, routine screening mammography will be more difficult. The patient should continue to perform monthly breast examinations for cancer screening; however, this may be more difficult. The implant may interfere with finding breast cancer during mammography. Because the breast and implant is squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast implants; therefore, a patient will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays.

Patients should be instructed to inform their mammographers about the presence, type and placement of their implants. Patients should be advised to request **diagnostic mammography** rather than **screening mammography**.

Presurgical mammography with a follow-up mammogram 6 months to 1 year following surgery may be performed to establish a baseline for future routine mammography.

RADIATION TO THE BREAST

INAMED has not tested the in-vivo effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy does not compromise implant integrity, but may increase the likelihood of capsular contracture, necrosis, and extrusion.

LONG-TERM EFFECTS

Patient Counseling Information

Although clinical study follow-up data has been collected through 4 years, the long-term safety and effectiveness of INAMED's Silicone-Filled Breast Implants has not been established. INAMED's 10-year Core Clinical Study is monitoring the long-term risk of breast implants, such as implant rupture, reoperation, implant removal, breast disease and other local and systemic complications.

SPECIAL CONSIDERATIONS & RISKS TO BE DISCUSSED WITH THE PATIENT

Patient Counseling Information

The following information should be discussed with patients prior to their decision to proceed with surgery:

- **Professional Care** – Patients should be advised that follow-up exams as prescribed by their plastic surgeon are recommended to monitor the status of their breast implants.
- **Avoiding Damage during Treatment** – Patients should be instructed to inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- **Smoking** – Patients should be informed that smoking may interfere with the healing process.
- **Breast Examination Techniques** – Patients should be instructed to follow the most current medical recommendations regarding breast examination and mammography frequency appropriate for their age and medical history. To maximize the effectiveness of breast self examinations for any palpable lesions, patients should be instructed how to distinguish the implant from breast tissue.

COMPLICATIONS

- **Rupture** – Patients should be informed that silicone gel-filled breast implants are not lifetime devices and that there is a potential for implant rupture. The decision to remove a ruptured or suspected ruptured implant should be undertaken following review of all available clinical information and after careful consideration between you and your patient. However, if implant rupture is diagnosed, it is recommended that the implant be removed.
- **Clinical Management of Suspected and Confirmed Rupture** – Patients should be informed that following a diagnosis of suspected or confirmed rupture that implant removal might be recommended by their surgeon, particularly in those instances where there may be evidence that silicone gel has moved beyond the confines of the fibrous capsule that typically forms around the device. Most surgeons in INAMED’s clinical studies have chosen to remove implants suspected of rupture.

Patients should be aware that, rarely, an intracapsular rupture may progress to an extracapsular rupture. Studies of Danish women indicate that over a 2-year period, about 10% of the implants with intra-capsular rupture progressed to extracapsular rupture as detected by MRI, i.e. for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women will have progression of the gel outside the scar tissue capsule. In about half of these cases of progression from intra- to extra-capsular rupture, the women had experienced trauma or mammography. In the other half, no cause was given.

In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of these women, i.e. for 100 women with silicone gel rupture outside the scar tissue capsule, the amount of gel outside the scar tissue capsule increased for 14 women 2 years later. This type of information is not available for INAMED-specific implants and it pertains to a variety of silicone implants from a variety of manufacturers and implant models.

- **Monitoring for Asymptomatic “Silent” Implant Rupture** – Patients should be informed that periodic evaluation of the integrity of their breast implants is required to determine whether the implant has ruptured in the absence of any clinical symptoms. While there are various diagnostic methods available to evaluate for possible implant rupture including physical examination, mammogram, and ultrasound, FDA believes the best method for detection of rupture is Magnetic Resonance Imaging (MRI). In most cases, an MRI diagnosis of rupture or possible rupture is consistent with a ruptured implant at explantation (Brown et al. 2000, Holmich et al. 2004). However, the scientific value of MRI is still developing. INAMED’s clinical study results and other published reports have found that in some cases MRI may falsely show a breast implant rupture when there is none (false positive). In some cases MRI may also show no breast implant rupture

when there is one (false negative). Scaranelo et al. (2004) found that the sensitivity and specificity of MRI to detect rupture in asymptomatic patients was 64% and 77%, respectively. Thus, MRI findings of rupture should not be considered definitive (Scaranelo et al. 2004).

Health Canada and the Canadian Expert Advisory Panel on silicone gel-filled breast implants advocate the following approach to monitor patients with breast implants. Patients should continue to perform routine breast self-examinations after their breast implant surgery and report any new symptom or unusual observation to their physician. Physicians should include breast exams as part of any breast implant patient's routine physicals. If, during a routine physical exam or an exam performed as a result of a suspicious finding reported by a patient, the physician determines that additional investigation is warranted, an ultrasound and/or mammogram should be performed. If the ultrasound is negative or inconclusive an MRI should then be performed. Based on this additional diagnostic testing, if a rupture is suspected, explantation should be considered.

- **Reoperation (Additional Surgeries)** – Patients should be advised that additional surgery to their breast and/or implant may be necessary over the course of their life.
- **Capsular Contracture** – Patients should be advised that capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in revision patients than in primary augmentation or reconstruction patients. Capsular contracture is also a risk factor for implant rupture, and it is one of the most common reasons for reoperation.
- **Explantation (Implant Removal)** – Patients should be advised that implants are not considered lifetime devices, and they will potentially undergo implant removal, with or without replacement, over the course of their life. Patients should also be advised that the changes to their breast following explantation are irreversible.
- **Infection** – In rare instances, acute infection may occur in a breast with implants. The signs of acute infection include erythema, tenderness, fluid accumulation, pain and fever. Very rarely, Toxic Shock Syndrome, a potentially life-threatening condition, has been reported in women after breast implant surgery. It is characterized by symptoms that occur suddenly and include high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and drops in blood pressure, which may cause fainting. Patients should be advised to contact a physician immediately for diagnosis and treatment for any of these symptoms.
- **Cosmetic Dissatisfaction (Unsatisfactory Results)** – Patients should be informed that dissatisfaction with cosmetic results related to such things as scar deformity, hypertrophic scarring, capsular contracture, asymmetry, displacement, incorrect size, unanticipated contour, and palpability may occur. Careful surgical planning and technique can minimize, but not preclude, the risk of such

results. Pre-existing asymmetry may not be entirely correctable. Physiological and behavioral differences among patients and variations in surgical techniques and medical treatments account for a wide variety of responses to silicone gel-filled breast implant surgery. Revision surgery may be indicated to maintain patient satisfaction but carries additional considerations and risks.

- **Breast Feeding** - Difficulties have been reported following breast surgery, including breast reduction and breast augmentation. A periareolar surgical approach may further increase the chance of breast feeding difficulties.
- **Additional Complications** – After breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: pain, hematoma/seroma, changes in nipple and breast sensation, extrusion, necrosis, delayed wound healing, and breast tissue atrophy/ chest wall deformity. Calcium deposits can form in the tissue capsule surrounding the implant with symptoms that may include pain and firmness. Lymphadenopathy has also been reported in some women with implants.

OTHER REPORTED CONDITIONS

Patient Counseling Information

There have been reports of other conditions in women with breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause and effect relationship has been established between breast implants and the conditions listed below. There is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants.

- **Connective Tissue Disease**

Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease (≤ 2) would need to be very large. Published studies taken together show that breast implants are not significantly associated with a risk of developing a specific connective tissue disease. These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific CTD diagnoses and symptoms in women with silent ruptured versus intact implants, but the study was too small to rule out a small risk.

- **Cancer**

Breast Cancer – Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer. Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect survival of women with breast cancer.

Brain Cancer – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population. The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.

Respiratory/Lung Cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants. Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery.

Cervical/Vulvar Cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants. The cause of this increase is unknown.

Other Cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population. This increase was not significant when compared to women who had other types of plastic surgeries.

- **Neurological**

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.

- **Mental Health Disorders**

Patients should be encouraged to discuss any history of mental health disorders, including a clinical diagnosis of depression, body dysmorphic disorder or eating disorder with you during their consultation visit(s). Patients with a diagnosis of depression or other mental health disorder should be encouraged to wait to schedule surgery until these conditions resolve.

- **Suicide**

In several studies, a higher incidence of suicide was observed in women with breast implants. The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.

- **Effects on Children**

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery. Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding. One of the authors of these human studies recommended further research on infant health.

- **Gel Bleed and Potential Health Consequences**

Small quantities of low molecular weight (LMW) siloxane compounds and platinum (in a zero valance/biocompatible state), have been found to diffuse (“bleed”) through an intact implant shell. Studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture and lymphadenopathy. Other studies have shown evidence of silicone in scar tissue capsules surrounding the implant, in axillary lymph nodes, and in distant organs, which may be due to gel bleed. The clinical significance of the presence of silicone in these tissues is unknown. Other studies have reported that certain silicones (for example, D4 and D5) and platinum leak from intact breast implants and are present in surrounding tissue. The clinical significance to humans of the presence of silicone in the body tissues is unknown. However, there has been no evidence in the medical literature or from INAMED’s own testing associating gel bleed with local complications in breast implant patients. Studies have demonstrated that the low concentration of platinum contained in breast implants is in the zero valance or most biocompatible state.

- **Delayed-type Hypersensitivity**

While there is no scientific evidence that silicone can cause hypersensitivity reactions in humans,

some animal testing reports in the literature suggest evidence of a delayed-type hypersensitivity to silicone. The biological mechanism and outcome for these findings in animal models remain unknown.

PRECLINICAL STUDY INFORMATION

Preclinical study of INAMED's Silicone-Filled Breast implants revealed that the materials of which the device is made are biocompatible, the silicone elastomer shell is durable, and there is a low potential for gel bleed (diffusion). A summary of the preclinical studies conducted by INAMED, including chemistry, toxicology, and physical/mechanical testing can be found in the Summary Basis for Decision (SBD) document on Health Canada's website at www.hc-sc.gc.ca.

Retrieval Study

INAMED's retrieval study analyses of returned ruptured devices identified surgical damage as one potential cause of implant rupture. Based on the study findings, there is a potential for damage to the implant during surgery if proper care is not taken. Information from the retrieval study on how to minimize failures related to the surgical procedure is discussed under "Warnings" on page 4. INAMED is continuing to study the correlation between surgical factors and device rupture.

INAMED CLINICAL STUDIES

Overview of INAMED's Core Clinical Study

The INAMED Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Patient follow-up is at 0-4 weeks, 6 months, 12 months, 24 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) is assessed by patient satisfaction and measures of body image/esteem and self esteem.

The INAMED Core Study consisted of 715 patients. This includes 455 augmentation patients, 147 revision-augmentation patients, 98 reconstruction patients, and 15 revision-reconstruction patients. The study is currently ongoing, with the results through 4 years reported in this brochure. INAMED will periodically update this brochure as more information becomes available.

INAMED's Core Study results indicate that the risk of any complication at some point through 4 years after implant surgery is 41.3% for primary augmentation patients and 56.9% for revision-augmentation patients. However, the majority of women were satisfied with their implants. The results also indicate that the chance of additional surgery (reoperation) through the first 4 years is 1 in 4 for primary augmentation patients (with capsule procedures as the most common type of additional surgery), and 1 in 3 for revision-augmentation patients (with the most common type of additional surgery being capsule procedures). The information below provides more details about the complications and benefits of Inamed's silicone-filled breast implants.

INAMED also conducted another study called the Adjunct Study, which reports complications for a large number of reconstruction and revision patients (no primary augmentation patients were part of this study) at 1, 3, and 5 years. Because of the low follow-up rates, which make the data of limited value, Adjunct Study data are not provided in this Directions for Use.

AUGMENTATION AND REVISION OF AUGMENTATION PATIENTS

Described below are the benefits and complications reported in the INAMED Core Study for augmentation patients. The findings are described separately for primary augmentation and revision-augmentation patients.

Patient Accounting (Follow-Up Rates)

The Core Study enrolled 455 augmentation patients. Of the women expected to be seen at the 4-year follow-up visit, 83% were seen.

The Core Study enrolled 147 revision-augmentation patients. Of the women expected to be seen at the 4-year follow-up visit, 82% were seen.

Effectiveness Outcomes

The benefits of silicone gel-filled breast implants were assessed by a variety of outcomes, including bra cup size change and assessments of patient satisfaction, body image, body esteem, and self concept. Data were collected before implantation and at scheduled follow-up visits for those patients who still had their original implants and who came back for these visits.

Primary Augmentation Patients:

For primary augmentation patients, 396 of the original 455 patients had a breast measurement within 18 months of surgery. Of these 396 patients, 41% increased by 1 cup size; 45% increased by 2 cup sizes; 8% increased by more than 2 cup sizes; and 6% had no increase or decreased.

Inamed's satisfaction assessment was based on patients' ratings of satisfaction with their implants at the time of the follow-up visits. 364 (80%) of the original 455 patients provided a satisfaction rating at 4 years after implantation with 95% of these patients indicating that they were satisfied with their breast implants.

For primary augmentation patients, the SF-36, which measures mental and physical health, showed a slight improvement in one scale and a slight worsening in another scale after 4 years compared to before breast implantation, although all scales remained higher than the general U.S. female population. For patient responses to questions regarding overall self-concept/self-esteem, there was a decrease in self-concept on the Tennessee Self Concept Scale and no change in overall self esteem on the Rosenberg Self Esteem Scale 4 years after receiving implants. Patient responses to questions on the Body Esteem Scale regarding overall self esteem related specifically to one's body did not show a change 4 years after receiving implants, but body esteem related to sexual attractiveness did show an increase in primary augmentation patients.

Revision-Augmentation Patients:

Revision-augmentation patients did not undergo a measurement of breast cup size change because they were undergoing replacement of an existing breast implant.

Inamed's satisfaction assessment was based on patients' ratings of satisfaction with their implants at the time of the follow-up visits. 111 (76%) of the original 147 revision-augmentation patients provided a satisfaction rating at 4 years. Of these 111 patients, 87% indicated that they were satisfied with their breast implants.

For revision-augmentation patients, the SF-36, which measures mental and physical health, showed no significant changes in these scales after 4 years. Patient responses to questions on the Tennessee Self Concept Scale, Rosenberg Self Esteem Scale and Body Esteem Scale regarding overall self-concept/self-esteem and body esteem showed no changes 4 years after receiving implants.

Safety Outcomes

Table 1 below describes the complications experienced by primary augmentation patients in the Core Study.

Table 1
Primary Augmentation: Complications

4-Year Cumulative First Occurrence Kaplan-Meier Risk Rates, By Patient

Complication*	Rate (%)	(95% CI)
Reoperation	23.5%	(19.5%, 27.5%)
Capsular Contracture III/IV	13.2%	(10.0%, 16.3%)
Breast Pain	8.2%	(5.6%, 10.7%)
Swelling	7.8%	(5.3%, 10.2%)
Implant Removal with Replacement	7.5%	(5.0%, 10.0%)
Nipple Sensation Changes	4.9%	(2.9%, 6.9%)
Implant Malposition	4.1%	(2.3%, 6.0%)
Hypertrophic Scarring	3.7%	(1.9%, 5.5%)
Asymmetry	3.2%	(1.6%, 4.9%)
Implant Rupture (MRI cohort)	2.7%	(0.1%, 5.3%)
Implant Removal without Replacement	2.3%	(0.8%, 3.7%)
Hematoma	1.6%	(0.4%, 2.7%)
Ptosis	1.4%	(0.3%, 2.5%)
Skin Sensation Changes	1.4%	(0.3%, 2.4%)
Seroma/Fluid Accumulation	1.3%	(0.3%, 2.4%)
Bruising, Delayed Wound Healing, Implant Extrusion, Implant Palpability/Visibility, Infection, Other Nipple Related Observation, Redness, Skin Rash, Tissue/Skin Necrosis, Wrinkling/Rippling	<1%	N/A
Capsule Calcification, Irritation, Lymphadenopathy, Lymphedema, Other Complications, Pneumothorax	0%	N/A

*Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excludes mild and very mild ratings). All occurrences or reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.

Table 2 below describes the complications experienced by revision-augmentation patients in the Core Study.

Table 2
Revision-Augmentation: Complications
4-Year Cumulative First Occurrence Kaplan-Meier Risk Rates, By Patient

Complication*	Rate (%)	(95% CI)
Reoperation	35.3%	(27.3%, 43.3%)
Capsular Contracture III/IV	17.0%	(10.7%, 23.4%)
Implant Removal with Replacement	10.5%	(5.3%, 15.7%)
Breast Pain	7.8%	(3.3%, 12.2%)
Swelling	6.4%	(2.3%, 10.4%)
Hypertrophic Scarring	6.1%	(2.0%, 10.1%)
Implant Palpability/Visibility	6.0%	(2.0%, 10.1%)
Asymmetry	5.1%	(1.4%, 8.8%)
Seroma/Fluid Accumulation	5.0%	(1.4%, 8.6%)
Implant Malposition	4.6%	(1.0%, 8.2%)
Implant Rupture (MRI cohort)	4.0%	(0.0%, 9.5%)
Wrinkling/Rippling	3.9%	(0.5%, 7.3%)
Ptosis	3.1%	(0.1%, 6.2%)
Implant Removal without Replacement	3.1%	(0.1%, 6.2%)
Bruising	2.1%	(0.0%, 4.4%)
Hematoma	2.1%	(0.0%, 4.4%)
Infection	1.4%	(0.0%, 3.3%)
Infection	1.4%	(0.0%, 3.3%)
Delayed Wound Healing, Irritation, Other Complications, Redness, Skin Rash	<1%	N/A
Capsule Calcification, Implant Extrusion Lymphadenopathy, Lymphedema, Nipple Sensation Changes, Other Nipple Related Observation, Pneumothorax, Tissue/Skin Necrosis	0%	N/A

*Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excludes mild and very mild ratings). All occurrences of reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.

Other Events

Through 4 years, events other than the complications described in the previous tables were collected in the Core Study for augmentation and revision-augmentation patients. Some of these events, such as breast cancer and CTD, can occur in non-implanted patients. Therefore, without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and some of these other events. CTD and breast cancer events were less than 1%. Events equal to or greater than 1% are described in Tables 3 and 4.

Table 3
Primary Augmentation: Other Events

Other Event	4-Year Rate by Patient
Benign Breast Disease	10%
Biopsy Procedure	3%
Unknown Breast Disease (i.e., not yet diagnosed)	1%

Table 4
Revision-Augmentation: Other Events

Other Event	4-Year Rate by Patient
Benign Breast Disease	11%
Biopsy Procedure	9%

Reasons for Reoperation

Table 5 below provides the main reason for each reoperation performed through 4 years in primary augmentation patients.

Table 5
Primary Augmentation: Main Reason for Reoperation through 4 Years

Reason for Reoperation	n	% (of 135 Reoperations)
Capsular Contracture	39	28.9%
Implant Malposition	21	15.6%
Ptosis	19	14.1%
Need for Biopsy	12	8.9%
Hematoma/Seroma	9	6.7%
Scarring	8	5.9%
Patient Request for Style/Size Change	7	5.2%
Implant Rupture	6	4.4%
Asymmetry	5	3.7%
Delayed Wound Healing	3	2.2%
Breast Cancer, Implant Extrusion, Infection, Necrosis, Nipple Complications, Pain	1 each	<1%

Table 6 below provides the main reason for each reoperation performed through 4 years in revision-augmentation patients.

Table 6
Revision-Augmentation: Main Reason for Reoperation through 4 Years

Reason for Reoperation	n	% (of 83 Reoperations)
Capsular Contracture	14	16.9%
Hematoma/Seroma	11	13.3%
Ptosis	9	10.8%
Scarring	8	9.6%
Need for Biopsy	8	9.6%
Implant Malposition	6	7.2%
Implant Rupture	4	4.8%
Asymmetry	3	3.6%
Delayed Wound Healing	3	3.6%
Nipple Complications	3	3.6%
Patient Request for Style/Size Change	3	3.6%
Breast Cancer	2	2.4%
Implant Extrusion	2	2.4%
Infection	2	2.4%
Breast Tissue Contour Deformity, Pain, Implant Palpability/Visibility, Injury, Wrinkling/Rippling	1 each	<1%

Reasons for Implant Removal

The main reasons for implant removal among primary augmentation patients in the Core Study over the 4 years are shown in Table 7 below.

Table 7
Primary Augmentation: Main Reason for Implant Removal through 4 Years

Reason for Reoperation	n	% (of 77 Explants)
Capsular Contracture	27	35.1%
Patient Request for Style/Size Change	18	23.4%
Implant Malposition	9	11.7%
Implant Rupture	7	9.1%
Ptosis	6	7.8%
Asymmetry	5	6.5%
Pain	2	2.6%
Breast Cancer, Hematoma/Seroma, Implant Extrusion	1 each	<1%

The main reasons for implant removal among revision-augmentation patients in the Core Study over the 4 years are shown in Table 8 below.

Table 8
Revision-Augmentation: Main Reason for Implant Removal through 4 Years

Reason for Reoperation	n	% (of 32 Explants)
Capsular Contracture	9	28.1%
Patient Request for Style/Size Change	6	18.8%
Implant Malposition	5	15.6%
Implant Rupture	4	12.5%
Ptosis	2	6.3%
Scarring	2	6.3%
Asymmetry, Breast Cancer, Infection, Pain	1 each	<1%

RECONSTRUCTION AND REVISION OF RECONSTRUCTION PATIENTS

Patient Accounting (Follow-Up Rates)

The Core Study enrolled 98 reconstruction patients. Of the women expected to be seen at the 4-year follow-up visit, 89% were seen.

The Core Study enrolled 15 revision-reconstruction patients. Of the women expected to be seen at the 4-year follow-up visit, 100% were seen.

Effectiveness Outcomes

The benefits of silicone gel-filled breast implants were assessed by a variety of outcomes, including bra cup size change and assessments of patient satisfaction, body image, body esteem, and self concept. Data were collected before implantation and at scheduled follow-up visits for those patients who still had their original implants and who came back for these visits.

Primary Reconstruction Patients:

Inamed's satisfaction assessment was based on patients' ratings of satisfaction with their implants at the time of the follow-up visits. 67 (68%) of the original 98 patients provided a satisfaction rating at 4 years after implantation with 94% of these patients indicating that they were satisfied with their breast implants.

For primary reconstruction patients, the SF-36, which measures mental and physical health, showed no changes after 4 years compared to before breast implantation. For patient responses to questions regarding overall self-concept/self-esteem, there was no change in self-concept on the Tennessee Self Concept Scale and no change in overall self esteem on the Rosenberg Self Esteem Scale 4 years after receiving implants. Patient responses to questions on the Body Esteem Scale regarding overall self esteem related specifically to one's body also did not show a change 4 years after receiving implants.

Revision-Reconstruction Patients:

Inamed's satisfaction assessment was based on patients' ratings of satisfaction with their implants at the time of the follow-up visits. 13 (87%) of the original 15 revision-reconstruction patients provided a satisfaction rating at 4 years. Of these 13 patients, 92% indicated that they were satisfied with their breast implants.

For revision-reconstruction patients, responses were similar pre- and post-implantation on the SF-36, Tennessee Self Concept Scale, Rosenberg Self Esteem Scale and Body Esteem Scale.

Safety Outcomes

Table 9 below describes the complications experienced by primary reconstruction patients in the Core Study.

Table 9
Primary Reconstruction: Complications
4-Year Cumulative First Occurrence Kaplan-Meier Risk Rates, By Patient

Complication*	Rate (%)	(95% CI)
Reoperation	40.9%	(31.0%, 50.8%)
Implant Removal with Replacement	18.3%	(10.4%, 26.2%)
Asymmetry	16.4%	(8.7%, 24.0%)
Capsular Contracture III/IV	14.1%	(7.0%, 21.2%)
Implant Removal without Replacement	7.8%	(1.8%, 13.9%)
Swelling	7.2%	(2.1%, 12.4%)
Wrinkling/Rippling	6.0%	(0.8%, 11.2%)
Infection	4.2%	(0.2%, 8.3%)
Implant Malposition	3.3%	(0.0%, 7.0%)
Breast Pain	3.1%	(0.0%, 6.5%)
Implant Extrusion	2.3%	(0.0%, 5.4%)
Tissue/Skin Necrosis	2.3%	(0.0%, 5.4%)
Hypertrophic Scarring	2.1%	(0.0%, 4.9%)
Skin Rash	2.0%	(0.0%, 4.8%)
Redness	1.1%	(0.0%, 3.3%)
Bruising	1.0%	(0.0%, 3.0%)
Nipple Sensation Changes	1.0%	(0.0%, 3.0%)
Ptosis	1.0%	(0.0%, 3.0%)
Capsule Calcification, Delayed Wound Healing, Hematoma, Implant Palpability/Visibility, Implant Rupture (MRI cohort), Irritation, Lymphadenopathy, Lymphedema, Other Complications, Other Nipple Related Observation, Pneumothorax, Seroma/Fluid Accumulation, Skin Sensation Changes	0%	N/A

*Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excluding mild and very mild ratings). All reports of reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.

Table 10 below describes the complications experienced by the revision-reconstruction patients in the Core Study.

Table 10
Revision-Reconstruction: Complications
4-Year Cumulative First Occurrence Rates*, By Patient

Complication**	Rate (%)	(95% CI)
Reoperation	33.3%	(11.8%, 61.6%)
Asymmetry	13.3%	(1.7%, 40.5%)
Implant Malposition	13.3%	(1.7%, 40.5%)
Breast Pain	6.7%	(0.2%, 31.9%)
Bruising	6.7%	(0.2%, 31.9%)
Capsular Contracture III/IV	6.7%	(0.2%, 31.9%)
Delayed Wound Healing	6.7%	(0.2%, 31.9%)
Hypertrophic Scarring	6.7%	(0.2%, 31.9%)
Implant Palpability/Visibility	6.7%	(0.2%, 31.9%)
Seroma/Fluid Accumulation	6.7%	(0.2%, 31.9%)
Wrinkling/Rippling	6.7%	(0.2%, 31.9%)
Capsule Calcification, Hematoma, Implant Extrusion, Implant Removal, Implant Rupture (MRI cohort), Infection, Irritation, Lymphadenopathy, Lymphedema, Nipple Sensation Changes, Other Complications, Other Nipple Related Observation, Pneumothorax, Ptosis, Redness, Skin Rash, Skin Sensation Changes, Swelling, Tissue/Skin Necrosis	0%	N/A

* Calculated as a percentage of enrolled with binomial confidence interval.

**Most events were assessed with severity ratings, and the rates shown in the table include only complications rated moderate, severe or very severe (excluding mild and very mild ratings). All reports of reoperation, implant removal, implant rupture, implant extrusion and pneumothorax are included.

Other Events

Through 4 years, events other than the complications described in the previous tables were collected in the Core Study for reconstruction and revision-reconstruction patients. Some of these events, such as breast cancer and CTD, can occur in non-implanted patients. Therefore, without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and some of these other events. Events equal to or greater than 1% are described in Tables 11 and 12.

Table 11
Primary Reconstruction: Other Events

Other Event	4-Year Rate by Patient
Benign Breast Disease	15%
Malignant Breast Cancer	8%
Biopsy Procedure	6%
CTD - Systemic Sclerosis/Scleroderma	1%

Table 12
Revision-Reconstruction: Other Events

Other Event	4-Year Rate by Patient
Benign Breast Disease	13%

Reasons for Reoperation

Table 13 below provides the main reason for each reoperation performed through 4 years in primary reconstruction patients.

Table 13
Primary Reconstruction: Main Reason for Reoperation through 4 Years

Reason for Reoperation	n	% (of 54 Reoperations)
Implant Malposition	12	22.2%
Capsular Contracture	10	18.5%
Asymmetry	8	14.8%
Hematoma/Seroma	6	11.1%
Need for Biopsy	3	5.6%
Ptosis	3	5.6%
Scarring	3	5.6%
Breast Tissue Contour Deformity	2	3.7%
Implant Extrusion	2	3.7%
Patient Request for Style/Size Change	2	3.7%
Delayed Wound Healing	1	1.9%
Implant Rupture	1	1.9%
Necrosis	1	1.9%

Table 14 below provides the main reason for each reoperation performed through 4 years in revision-reconstruction patients.

Table 14
Revision-Reconstruction: Main Reason for Reoperation through 4 Years

Reason for Reoperation	n	% (of 7 Reoperations)
Nipple Complications	4	57.1%
Scarring	2	28.6%
Capsular Contracture	1	14.3%

Reasons for Implant Removal

The main reasons for implant removal among primary reconstruction patients in the Core Study over the 4 years are shown in Table 15 below.

Table 15
Primary Reconstruction: Main Reason for Implant Removal through 4 Years

Reason for Reoperation	n	% (of 28 Explants)
Implant Malposition	8	28.6%
Capsular Contracture	7	25.0%
Asymmetry	4	14.3%
Patient Request for Style/Size Change	4	14.3%
Hematoma/Seroma	2	7.1%
Implant Extrusion	1	3.6%
Implant Rupture	1	3.6%
Necrosis	1	3.6%

There were no implant removals among revision-reconstruction patients in the Core Study over 4 years.

INSTRUCTIONS FOR USE

NOTE: Back-up breast implants should be available during the procedure.

DO NOT use more than one implant per breast.

Single Use

This product is intended for **single use only**. Do not reuse explanted implants.

Product Identification

Product identification stickers accompanying each device are provided within the internal product packaging. The stickers provide product-specific information and are designed to be attached to the patient's chart for identification purposes.

Surgical Planning

INAMED relies on the surgeon to know and follow the proper surgical procedures with INAMED Silicone-Filled Breast Implants. Proper surgical planning such as allowance for adequate tissue coverage, implant placement (i.e., submuscular vs. subglandular), incision site, implant type, etc., should be made preoperatively. The surgeon must carefully evaluate breast implant size and contour, incision placement, pocket dissection, and implant placement criteria with respect to the patient's anatomy and desired physical outcome. Planning should include clear delineation of aesthetic goals to ensure mutual understanding between surgeon and patient. The surgeon should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring, reactions.

Preliminary Product Examination

How to Open Sterile Product Package

Remove the sterile breast implant from its package in an aseptic environment and using talc-free gloved hands. **DO NOT** expose the breast implant to lint, talc, sponges, towels, or other contaminants.

1. Peel open the lid of the outer thermoform package.
2. Invert the outer thermoform package over the sterile field, allowing the sealed inner thermoform package to gently fall into the field.
3. Peel open the lid of the inner thermoform package using the pull-tab.

4. Gently retrieve the breast implant. Prior to use, keep the breast implant in the inner thermoform package to prevent contact with airborne and surgical field particulate contaminants.

Examination of Silicone Gel-Filled Breast Implants

Prior to use, examine the breast implant for evidence of any particulate contamination, damage, or loss of shell integrity. If satisfactory, return the breast implant to the inner thermoform tray and cover it with the lid until implanted to prevent contact with airborne contaminants.

DO NOT implant any device that may appear to have particulate contamination, damage, or loss of shell integrity. A sterile back-up implant must be readily available at the time of surgery.

DO NOT implant any device that may appear to have leaks or nicks.

DO NOT implant damaged or contaminated breast implants.

Sterile Product

Each sterile silicone-filled breast implant is supplied in a sealed, double primary package. Sterility of the implant is maintained only if the thermoform packages, including the package seals, are intact. Use standard procedures to maintain sterility during transfer of the breast implant to the sterile field. Remove the breast implant from its package in an aseptic environment and using talc-free gloved hands.

DO NOT use the product if the thermoform packages or seals have been damaged.

DO NOT resterilize the product.

Avoid unnecessary exposure of the breast implant to lint, talc, sponges, towels, skin oils, and other contaminants.

Prior to use, keep the breast implant in the inner thermoform and covered to prevent contact with airborne and surgical field particulate contaminants.

Method for Removing Ruptured Silicone Gel from the Surgical Pocket

In the event of breast implant rupture, the following technique is useful for removal of the silicone mass. Wearing double talc-free surgical gloves on one hand, use the index finger to penetrate the silicone mass. With the other hand, exert pressure on the breast to facilitate manipulation of the silicone mass into the double-gloved hand. Once the silicone is in hand, pull the outer glove over the

silicone mass and remove. To remove any residual silicone, blot the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the silicone. If contact occurs, use isopropyl alcohol to remove the silicone from the instruments. Ruptured breast implants must be reported and should be returned to INAMED. In the event of breast implant rupture, contact INAMED Product Support Department at 800.962.8728.

Surgical Procedure Placement

Ensure incision is sufficiently large to facilitate insertion without excessive manipulation and handling of the device and to avoid damage to the device. Inadequate pocket dissection increases the risk of rupture and implant malposition.

A sterile BIOCELL® Delivery Assistance Sleeve is available separately and can be used to assist with placement of the breast implant. Use of this sleeve for insertion of BIOCELL® textured breast implants provides a shell/tissue interface with less friction. Insert the implant into one end of the sleeve. Insert the proximal end of the sleeve into the surgically prepared pocket. With the tissue retracted, the sleeve can be twisted at its distal end to gently guide the breast implant into the pocket. Once the breast implant is inserted, gently remove the sleeve.

DO NOT use lubricants to facilitate placement. Their use creates the risk of pocket contamination and may also affect the tissue-capsule interface.

DO NOT damage the breast implant with sharp surgical instruments such as needles and scalpels, blunt instruments such as clamps and forceps, or by over handling and manipulation during introduction into the surgical pocket.

DO NOT use excessive force during breast implant placement.

DO NOT manipulate the implant for either radial expansion, compression or dissection of the pocket.

Breast augmentation with silicone gel-filled implants can be carried out through several different incisions including inframammary, periareolar, or transaxillary. Some surgeons advocate a “no-touch” technique, which requires significant attention to minimizing contact between the patient’s skin and the implant. Pocket dissection should be planned out preoperatively and be performed accurately and with minimal trauma. Excellent hemostasis is important to avoid postoperative hematoma. The implant may be placed subglandularly or subpectorally depending upon the balance of cosmetic and medical considerations in any given patient. The size and shape of the device may be determined preoperatively by means of dimensional planning or intraoperatively with the help of temporary sizer devices.

The incision for the placement of the implant should be securely closed and in several layers, whenever possible. Drains are optional.

Breast Reconstruction is generally carried out in the mastectomy scar. Special care must be used in breast reconstruction to make sure that appropriate amounts of healthy tissue are available to cover the implant and that the implant be properly sized and positioned based upon careful preoperative planning.

INAMED Academy® Educational Materials are available through INAMEDacademy.ca and INAMEDacademy.com to supplement surgical knowledge of the dimensional techniques intended for use with INAMED Aesthetics breast implants.

Maintaining Hemostasis/Avoiding Fluid Accumulation

Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly also by postoperative use of a closed drainage system. Persistent, excessive bleeding must be controlled before implantation.

Any postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination or damage from sharp instruments.

DOCUMENTATION THE PHYSICIAN SHOULD PROVIDE TO THE PATIENT

Breast implantation is an elective procedure and the patient must be well counseled on the risk-benefit relationship. The surgeon should provide each prospective patient with the following:

Patient Planner including Important Information for Women About Breast Augmentation/ Reconstruction with INAMED Silicone-Filled Breast Implants

This planner should be used to facilitate patient education on the risks and benefits of silicone gel-filled breast implant surgery. The applicable patient labeling (either augmentation or reconstruction) should be inserted into the pocket of Patient Planner and then the entire Planner should be given to the patient during her initial visit/consultation to allow sufficient time for review. You should verify

that the patient has an adequate understanding of the information provided by evaluating the Patient Self Assessment and using this as a foundation for subsequent preoperative discussion.

Device Identification Card

Enclosed with each silicone-filled breast implant is a Device Identification Card. To complete the Device Identification Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. Patients should be provided with these cards for personal reference.

ADDITIONAL SPECIFIC PRODUCT INFORMATION

BIOCELL® Delivery Assistance Sleeve

Sterile BIOCELL® Delivery Assistance Sleeves are available from your INAMED Aesthetics Sales Representative or Customer Care Department at 800.962.8728.

Returned Goods Policy

Product returns should be handled through an INAMED Aesthetics Sales Representative or through the Customer Care Department at 800.962.8728. Return value is based on time limitations. All package seals must be intact to be eligible for return. Returned products may be subject to a restocking charge.

Reporting and Return of Explanted Devices

The reason for explantation should be reported and the explanted device returned to INAMED Corporation. In the event of an explantation, please contact INAMED's Product Support Department at 800.962.8728 for an Explant Kit and explant return instructions.

ConfidencePlus™ Limited Warranties

The ConfidencePlus™ Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in implant rupture, subject to certain conditions as fully discussed in the ConfidencePlus™ literature. INAMED offers two levels of coverage under its warranty program. Our standard ConfidencePlus Limited Warranty program applies automatically to every INAMED breast implant recipient subject to the conditions discussed in the ConfidencePlus literature. The optional ConfidencePlus™ Platinum Limited Warranty program is

available for a low enrollment fee and increases the financial benefit in the event of implant rupture, subject to the conditions discussed in the ConfidencePlus literature. For more information, please contact INAMED's Product Support Department at 800.962.8728.

Product Ordering

To order directly in Canada or for product information, please contact your local INAMED Aesthetics Sales Representative or the INAMED Customer Care Department at 800.962.8728.

INAMED, the INAMED logo, BIOCELL, BioDIMENSIONAL, and ConfidencePlus are registered trademarks and/or trademarks of INAMED Corporation.

These products are covered by one or more of the following U.S. Patents: 5,480,430; 5,007,929; 4,889,744 and 4,859,712 and/or foreign patents corresponding thereto.

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