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Dear CSAPS and CSPS Members:

Many members of CSAPS and CSPS perform breast augmentation and breast reconstruction with implants in their practices. Changes and improvements to implants have occurred over the past 60 years such that implants currently approved by Health Canada have an extremely high satisfaction rate for patients choosing elective breast surgery or those requiring breast reconstructive surgery.

Recently there have been suggestions, circulating in public forums and in the general press, that breast implants may be responsible for a wide array of medical symptoms, collectively being referred to as "breast implant illness". As surgeons we know that there are potential risks/adverse events associated with all operations. It is also known that implants are never intended to be lifetime devices. Well-known local complications and adverse outcomes include infection, capsular contracture, implant migration and implant rupture. Extra-capsular rupture is also known to cause isolated regional swelling and intact capsules can become calcified resulting in scar tissue, pain and tenderness as in Baker IV capsular contracture. Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) represents a very rare but serious complication that we have recently become aware of; to date it seems to be uniquely associated with textured implants. Treatment includes implant and capsule removal. Previous bulletins published by CSPS and CSAPS have provide guidance to members regarding BIA-ALCL.

As alluded to above, the term breast implant illness is being used presently in the lay public and the press to describe a large constellation of symptoms and named medical conditions experienced by some patients with breast implants (Table 1). Similar

concerns arose around silicone breast implants in the 1990's and in turn led to an FDA and Health Canada moratorium on the use of silicone breast implants until the issue was further studied. The resulting investigations eventually led the National Academy of Science Institute of Medicine to conclude that there was no evidence to support an association between silicone breast implants and these systemic conditions. The FDA and Health Canada subsequently approved the reintroduction of silicone implants in the USA and Canada, respectively. At that time the FDA mandated that the manufacturers conduct ongoing studies monitoring health outcomes in implanted patients. These studies started enrolling patients in 2007.

While to date there still is not sufficient new scientific evidence showing that breast implants are causally associated with these systemic conditions, it is important to note that most of the named medical conditions on the list are rare health events in the general population. Conversely, many of the symptoms listed in table 1 are common in all members of the general population and arise from a myriad of aetiologies. As such we strongly support ongoing and new large scale surveillance and scientific scrutiny. In the United States, the FDA has partnered with the Plastic Surgery Foundation to create a National Breast Implant Registry. Attempts to do the same in Canada have been unsuccessful to date due to lack of Health Canada resources, however we continue to work on this issue.

Many of us have already seen patients in our practices requesting removal of their capsules and implants. Some patients may request en-bloc removal of the capsules and implants. Of patients who undergo removal of their implants, some, but not all have reported improvement in their symptoms. As well, complete removal of the implants and capsules can be a challenging undertaking associated with unsatisfactory aesthetic outcomes and other potential risk which may exceed the perceived benefit.

As plastic surgeons, we have a responsibility to precisely understand the concerns of our patients and remain current in our understanding of the safety of the medical devices that we recommend. In addition, we must make available to them honest and evidence-based advice; this includes referral for consultation by others with medical expertise in other areas of medicine. After collecting all of the necessary information we should come to mutual agreement on a treatment plan that is in the best interest of each patient.

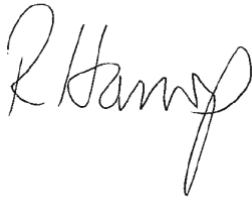
Presently science does not support a causal association between breast implants and this disparate constellation of systemic conditions referred to as breast implant illness. Nonetheless we strongly advocate for ongoing rigorous scientific research examining both the benefits and potential harm from breast augmentation and implant reconstruction in order to ensure that these procedures are performed with acceptable risks for informed patients.

If you have any questions or require any further information, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Bendor-Samuel". The signature is fluid and cursive, with a large initial "R" and "S".

Richard Bendor-Samuel, MD, FRCSC
President
Canadian Society for Aesthetic Plastic Surgery

A handwritten signature in black ink, appearing to read "Rob Harrop". The signature is cursive and somewhat stylized, with a large initial "R".

Rob Harrop MD, FRCSC, FACS
President
Canadian Society of Plastic Surgeons

DISCLAIMER

This document is not intended to define or serve as the standard of medical care. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all the circumstances. This document should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. This document reflects the state of current knowledge at the time of its publication and CSAPS will endeavour to update and revise this document periodically.

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Table 1.

FATIGUE
HEADACHES, MIGRANES AND OCULAR MIGRANES
BRAIN FOG, MEMORY LOSS
MUSCLE AND JOINT PAIN
SWOLLEN AND TENDER LYMPH NODES IN BREAST AREA, UNDERARM, THROAT, NECK, GROIN
ANXIETY, DEPRESSION AND PANIC ATTACKS
GENERAL CHEST DISCOMFORT SHORTNESS OF BREATH
POOR SLEEP AND INSOMNIA
HEART PALPITATIONS, CHANGES IN NORMAL HEART RATE OR HEART PAIN
FEELING LIKE YOU ARE DYING
SYMPTOMS OF FIBROMYALGIA
GENERAL CHEST DISCOMFORT SHORTNESS OF BREATH
LEAKY GUT, IBS AND SIBO
GASTROINTESTINAL ISSUES SUCH AS ACID REFLUX, GERD, GASTRITIS
PERSISTENT BACTERIAL, VIRAL, FUNGAL INFECTIONS
YEAST INFECTIONS, CANDIDA, SINUS AND UTI INFECTIONS
FEVERS, NIGHT SWEATS, INTOLERANT TO HEAT/COLD
HAIR LOSS, DRY SKIN AND HAIR
SKIN RASHES
HYPO/HYPER THYROID SYMPTOMS
HYPO/HYPER ADRENAL SYMPTOMS
PARATHYROID PROBLEMS
FREQUENT URINATION
NUMBNESS/TINGLING SENSATION IN UPPER AND LOWER LIMBS
PREMATURE AGING
WEIGHT PROBLEMS
INFLAMMATION
BODY ODOUR
DRY EYES, DECLINE IN VISION
HORMONE IMBALANCE, DIMINISHING HORMONES, EARLY MENOPAUSE
HYSTERECTOMY
LOW LIBIDO
SLOW HEALING, EASY BRUISING
THROAT CLEARING, COUGH, DIFFICULTY SWALLOWING, CHOKING, REFLUX
METALLIC TASTES
VERTIGO
PANCREATITIS
EAR RINGING
SUDDEN FOOD INTOLERANCE AND ALLERGIES
SLOW MUSCLE RECOVERY AFTER ACTIVITY
SORE AND ACHING JOINTS OF SHOULDERS, HIPS, BACKBONE, HANDS AND FEET
DEHYDRATION FOR NO REASON
COLD AND DISCOLORED LIMBS, HANDS AND FEET
PAIN AND OR BURNING SENSATION AROUND IMPLANT AND OR UNDERARM
LIVER AND KIDNEY DYSFUNCTION
GALLBLADDER PROBLEMS
TOXIC SHOCK SYMPTOMS
SYMPTOMS OF LYME DISEASE
SYMPTOMS OF EBV
SYMPTOMS OF AUTO-IMMUNE DISEASES SUCH AS;
RAYNAUD'S SYNDROME,
HASHIMOTO'S THYROIDITIS,
RHEUMATOID ARTHRITIS,
SCLERODERMA, LUPUS,
SJOGREN'S SYNDROME,
NONSPECIFIC CONNECTIVE TISSUE DISEASE,
MULTIPLE SCLEROSIS
SYMPTOMS OF BIA-ALCL LYMPHOMA
DIAGNOSIS OF CANCER