#### EXHIBIT A-2

#### MEDICAL CONDITIONS LIST

# MEDICAL CONDITIONS AND CHARACTERISTICS OUTLINE OF DEFINITIONS AND CLASSIFICATION CRITERIA

The procedures set forth herein for the definition and classification of medical conditions pursuant to the Dow Corning/Quebec Breast Implant Litigation Settlement Agreement (the "Agreement") were prepared by Settlement Class Counsel on behalf of the plaintiffs. The procedures set forth herein will be implemented by the Claims Administrator (and where applicable as set forth herein the Settlement Class Counsel,) subject to the ongoing authority and supervision of the Quebec Court. These provisions and procedures do not and are not intended to impose any responsibilities or obligations on Dow Corning and/or the Released Parties.

Settlement Class Members who are or were Dow Corning Breast Implant Recipients and who meet the diagnostic criteria for the medical conditions and symptom complexes listed herein and meet other requirements set forth in the Agreement will be compensated pursuant to the Agreement. Eligible Claimants who meet the diagnostic criteria will be classified and receive compensation in accordance with the Compensation Schedule, attached as Exhibit A-1 to the Agreement.

#### I. GENERAL GUIDELINES

- A. To make a claim for compensation for one of the Designated Medical Conditions defined below, a claimant must provide a statement or diagnosis from a Licensed Medical Specialist, as defined below, together with the medical records upon which that statement or diagnosis is based.
- B. A claimant should submit all records that contain information relevant to the diagnostic criteria set forth herein, including (1) records relating to the relevant signs, symptoms, findings and test results set forth hereunder and (2) records showing the severity of a claimant's disease or, if applicable, a Statement of Disability, as defined in Paragraph I.E, below. In general, whatever the Licensed Medical Specialist relied upon in arriving at the diagnosis and findings in the statement or diagnosis should be provided. This might include physical findings noted in the office chart, and certain lab or other test reports. If the Licensed Medical Specialist needed to review earlier medical records obtained from other physicians to make a definitive statement about the claimant's condition or disability, then those records must also be submitted.

Exhibit A-2
To The Dow Corning/Quebec
Breast Implant Litigation Settlement Agreement

## C. Licensed Medical Specialist

As used herein, the term "Licensed Medical Specialist" means a physician who (1) either is a specialist certified by the Canadian Board, a Fellow of the Royal College of Physicians and Surgeons or a physician who has been certified by the appropriate medical licensing board in any province of Canada, and (2) is licensed in internal medicine, rheumatology, neurology, neurological surgery or immunology. Only a Licensed Medical Specialist can submit the statement or diagnosis of one of the Designated Medical Conditions.

#### D. Documented

As used in the Agreement in relation to Supporting Medical Documentation, the term "documented" means that written notations of symptoms are found at several places in the claimants medical records. Thus, to show that the symptoms are documented, a claimant must submit medical records that reflect that the claimant had complained about these symptoms on more than one occasion. Except, however, that it may also mean that the Licensed Medical Specialist or licensed treating physician has verified the symptoms on physical examination and interviewed the claimant sufficiently to be able to form a professional opinion, utilizing all that doctor's knowledge and training to establish that the complaint is valid. In this situation, it is important that the Licensed Medical Specialist or licensed treating physician relying on such an examination and interview does not qualify the diagnosis by stating that his "findings" are based solely on the patient's history given at the time of the single visit to the Licensed Medical Specialist or licensed treating physician. The Licensed Medical Specialist diagnosing a Designated Medical Condition must be licensed in the specialty to which the Designated Medical Condition relates.

#### E. Statement of Disability

To the extent the severity of a claimant's disease is based on a disability, as defined herein, the claimant must submit all of the records that the Licensed Medical Specialist relied upon in making his or her assessment and determination of disability ("Statement of Disability"). This would include, as an example, any disability questionnaire that the claimant completed in order to assist in the physician's determination. A non-specialist treating physician can provide a Statement of Disability, however, the physician making the Statement of Disability cannot be either the claimant's usual personal doctor or a family relative of the claimant.

#### F. Severity/Disability Category A

With respect to claims for placement in Severity/Disability Category A, claimants, their physicians and their counsel, if applicable, should be aware that it is difficult to meet the criteria for Category A. A claimant must be unable to do any of her normal activities or be able to do only a very few of them. A claim for placement in Category A should be reviewed to determine whether the claimant's daily life and limitations have been described in sufficient detail to show the Claims Administrator that the claimant meets the strict definition of total disability. In addition, it must be clear that the claimant's Designated Medical Condition is the cause of her total disability. If the claimant's Licensed Medical Specialist or licensed treating physician determines that her death or total disability is clearly and specifically caused by a disease or occurrence that is not a Designated Medical Condition, the claimant will not be eligible for placement in Category A.

#### G. Severity/Disability Category B

With respect to a claim for placement in Severity/Disability Category B. the claim must be based on severe pain or an inability to do certain activities. In order to qualify, the claimant's Designated Medical Condition must cause pain-producing symptoms that result in severe pain on a regular or recurring basis. Generalized statements about "severe pain" may not be enough; the Claims Administrator must be able to verify that the symptoms of the Designated Medical Condition itself are the cause of the severe pain. If the claim for placement in Category B is based on limitations on a claimant's activities, the claim submission must provide information concerning the activities that are limited. A conclusory statement, with no information about the claimant and her limitations, may result in rejection of the claim or request for more information. Any Statement of Disability must demonstrate a connection between a Designated Medical Condition and the specific activities that the claimant can no longer perform. The disability must be due to the Designated Medical Condition. The Claims Administrator must have enough information about what the limitations are, and the cause of those limitations, to be able to verify that the claimant's condition indeed meets the requirements for placement in Category B.

# H. Severity/Disability Category C

A claim for placement in Severity/Disability Category C must be based on pain or an inability to do certain activities. In preparing claims for Medical Conditions Compensation and in curing any deficiencies that may be noted when the claim is processed, claimants, their physicians and their counsel, if applicable, should be aware that the Designated Medical

Condition must have caused the stated disability. For example, the pain must be due to the claimant's Atypical Connective Tissue Disease or Atypical Neurological Disease Syndrome (ANDS), as described below. Thus, a critical factor in the Claims Administrator's evaluation of an alleged disability category is whether the claimant's qualifying symptoms are ones such as alopecia, chronic fatigue or loss of breast function, that normally have no pain component. If the claim for placement in Category C is based on limitations on a claimant's activities, the claim submission must provide information concerning the activities that are limited. A conclusory statement, with no information about the claimant and her limitations, may result in rejection of the claim or request for more information. Any Statement of Disability must demonstrate a connection with the specific activities that the claimant can no longer perform. A disability determination cannot be approved unless there is evidence that the claimant is experiencing pain from at least one of the qualifying symptoms of a Designated Medical Condition. In addition, claimants, their physicians and their counsel, if applicable, should be aware that a Category C requires that the pain be "regular or recurring." Thus, if a claimant's pain is described in her records as being only "mild" or "slight," her claim will not qualify for placement in Category C.

#### II. DESIGNATED MEDICAL CONDITIONS

#### A. Systemic Sclerosis/Scleroderma ("Ss")

- 1. A diagnosis of systemic sclerosis shall be made in accordance with the criteria established in Kelley, et al., Textbook of Rheumatology (4th ed.) at 1113, et seq.
- 2. Application of these diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of classical SS but who nonetheless have a systemic sclerosis-like (scleroderma-like) disease, except that an individual will not be compensated in this category if her symptomology more closely resembles Mixed Connective Tissue Disease ("MCTD"), Atypical Connective Tissue Disease ("ACTD"), both as described below, or any other disease or condition defined below. A "systemic sclerosis-like" or "scleroderma-like" disease is defined as an autoimmune/rheumatic disease that fulfills most of the accepted standards for the diagnosis of SS but is in some manner atypical of SS.

#### 3. Severity/Disability Categories

#### a. <u>Category A</u>

Death or total disability resulting from SS or an SS-like condition. An individual will be considered totally disabled if the individual satisfies the functional capacity test set forth in Paragraph II.G.5.a, below, for Severity/Disability Category A for ACTD, Atypical Rheumatic Syndrome ("ARS") and Nonspecific Autoimmune Condition ("NAC"), both as described below, or if the individual suffers from systemic sclerosis with associated severe renal involvement manifested by a decrease in glomerular filtration rates.

#### b. Category B

Cardio-pulmonary involvement or diffuse (Type III) scleroderma as defined by Barnett, A Survival Study of Patients with Scleroderma Diagnosed Over 30 Years: (1953 - 1983) The Value of a Simple Cutaneous Classification in the Early Stages of the Disease, 15, The Journal of Rheumatology, 276 (1988), and Masi, Classification of Systemic Sclerosis (Scleroderma): Relationship of Cutaneous Subgroups in Early Disease to Outcome and Serologic Reactivity, 15 The Journal of Rheumatology 894 (1988).

# c. Category C

Other, including CREST, limited, or intermediate scleroderma; except that any individual who manifests either severe renal involvement, as defined above, or cardio-pulmonary involvement, will be compensated at either Category A or Category B as appropriate.

# d. Category D

Not covered above, including localized scleroderma.

# B. Systemic Lupus Erythematosus ("SLE")

1. A diagnosis of systemic lupus erythematosus ("SLE") shall be made in accordance with the "1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus," 25 Arthritis and Rheumatism No. 11 (November 1982) adopted by the American College of Rheumatology ("ACR"). See Kelly, et al., supra, (4th ed.), Table 61-11, at 1037. A diagnosis of lupus is made if four of

the eleven manifestations listed in the table were present, either serially or simultaneously, during any interval of observations.

CRITERION	DEFINITION
Malar rash	Fixed erythema, flat or raised, over the malar
	eminences, tending to spare the nasolabial folds
Discoid rash	Erythematous raised patches with adherent keratotic
	scaling and follicular plugging; atrophic scarring may
	occur in older lesions
Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by
	patient history or physician observation
Oral ulcers	Oral or nasopharyngeal ulceration, usually painless,
	observed by a physician
Arthritis	Nonerosive arthritis involving two or more peripheral
	joints, characterized by tenderness, swelling or effusion
Serositis	(a) Pleuritis – convincing history of pleuritic pain or
	rub heard by a physician or evidence of pleural
	effusion, or (b) Pericarditis-documented by ECG or
	rub or evidence of pericardial effusion
Renal disorder	(a) Persistent proteinuria greater than 0.5 g/day or
	greater than 3 + if quantitation not performed, or (b)
	Cellular casts – may be red cell, hemoglobin, granular,
	tubular, or mixed
Neurologic disorder	(a) Seizures – in the absence of offending drugs or
•	known metabolic derangements; e.g., uremia,
•	ketoacidosis, or electrolyte imbalance, or (b) Psychosis
	- in the absence of offending drugs or known
	metabolic derangements, e.g., uremia, ketoacidosis or
	electrolyte imbalance
Hematologic	(a) Hemolytic anemia – with reticulocytosis, or (b)
disorder	Leukopenia – less than 4000/mm total on 2 or more
	occasions, or (c) Lymphopenia – less than 1500/mm
	on 2 or more occasions, or (d) Thrombocytopenia –
	less than 100,000/mm in the absence of offending
	drugs
Immunologic	(a) Positivie LE cell preparation, or (b) Anti-DNA –
disorder	antibody to native DNA in abnormal titer, or (c) Anti-
	Sm – presence of antibody to Sm nuclear antigen, or
	(d) False positive serologic test for syphilis known to
	be positive for at least 6 months and confirmed by
	Treponema pallidum immobilization or fluorescent
A	treponemal antibody absorption test
Antinuclear antibody	, · ·
	immunofluorescence or an equivalent assay at any
	point in time and in the absence of drugs known to be
	associated with drug-induced lupus syndrome

2. Application of the ACR diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of SLE but who nonetheless have an SLE-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles MCTD, ACTD or any other disease or condition defined below.

#### 3. Severity/Disability Categories

#### a. Category A

Death or total disability resulting from SLE or an SLE-like condition. An individual will be considered totally disabled based on either the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS/NAC or severe renal involvement.

#### b. Category B

SLE with major organ involvement defined as SLE with one or more of the following: glomerulonephritis, central nervous system involvement (i.e., seizures or Lupus Psychosis), myocarditis, pneumonitis, thrombocytopenic purpura, haemolytic anemia (marked), severe granulocytopenia, mesenteric vasculitis. See Immunological Diseases, Max Samter, Ed., Table 56-6, at 1352.

# c. Category C

Non-major organ SLE requiring regular medical attention, including doctor visits and regular prescription medications. An individual is not excluded from this category for whom prescription medications are recommended but who, because of the side effects of those medications, chooses not to take them.

# d. Category D

Non-major organ SLE requiring little or no treatment. An individual will fall into this category if she is able to control her symptoms through the following kinds of conservative measures: over-the-counter medications, avoiding sun exposure, use of lotions for skin rashes and increased rest periods.

# C. Atypical Neurological Disease Syndrome ("ANDS")

- 1. A diagnosis of Atypical Neurological Disease Syndrome ("ANDS") shall be based on the clinical findings and laboratory tests set forth below. The clinical and laboratory presentation of these neurological syndromes will have an atypical presentation from the natural disease and will also have additional neuromuscular, rheumatic or nonspecific autoimmune signs and symptoms.
- 2. Eligibility for ANDS requires both
  - a. satisfying the requirements for one of the four neurological disease types set forth in Paragraph II.C.5, below; and
  - b. any three additional (nonduplicative) neuromuscular, rheumatic, or nonspecific symptoms or findings set forth in the definition for ACTD in Paragraph II.4.a, below.
- 3. An individual will fit into this category if her primary symptoms are characteristic of a neurological disease as diagnosed by a Licensed Medical Specialist.
- 4. If the individual's Licensed Medical Specialist determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be utilized in the diagnosis of ANDS. A symptom that may be caused only in part by a source other than breast implants is not excluded from such utilization.
- 5. Neurological Disease Types
  - a. Polyneuropathies

This disease category requires a diagnosis of a polyneuropathy that is confirmed by one or more of the following:

- (1) objectively-demonstrated loss of sensation to pinprick, vibration, touch or position;
- (2) proximal or distal muscle weakness;
- (3) tingling and/or burning pain in the extremities;
- (4) signs of dysesthesia; or
- (5) loss of tendon reflex; and one or more of the following laboratory findings:

- (6) abnormal levels of anti-mag or anti-sulfatide or anti-GM 1 antibodies;
- (7) abnormal sural nerve biopsy; or
- (8) abnormal electrodiagnostic testing (EMG or nerve conduction studies, etc.).

#### b. Multiple Sclerosis-Like Syndrome

This disease category requires definite evidence of central nervous system disease, with history and physical findings compatible with Multiple Sclerosis or Multiple Sclerosis-Like Syndrome, involving one or more of the following signs and symptoms:

- (1) weakness in the pyramidal distribution;
- (2) evidence of optic neuritis documented by ophthalmologist;
- (3) increased deep tendon reflexes;
- (4) absent superficial abdominal reflexes;
- (5) ataxia or dysdiadochokinesia as the sign of cerebellar involvement;
- (6) neurologically induced tremors; or
- (7) internuclear ophthalmoplegia and/or bladder or speech involvement secondary to central nervous system disease;

and one or more of the following:

- (8) abnormal Brain MRI with foci of increased signal abnormality suggestive of demyelinating lesions;
- (9) delayed visual-evoked responses or abnormal-evoked potentials; or
- (10) abnormal CSF with olioclonal bands.

## c. ALS-Like Syndrome

This disease category requires documented evidence of progressive upper and widespread lower motor neuron disease and/or bulbar involvement, and one or more of the following:

- (1) neurological autoantibodies such as anti-mag, antisulfatide or anti-GM 1;
- (2) abnormal sural nerve biopsy;
- (3) chronic inflammation on muscle or nerve biopsies;
- (4) abnormal EMG; or
- (5) documentation on exam of both upper and lower motor neuron disease and/or bulbar involvement.

#### d. Disease of Neuromuscular Junction

This disease category requires either (1) a diagnosis of Myasthenia Gravis or Myasthenia Gravis-like syndrome or disorders of the neuromuscular junction, made by a Licensed Medical Specialist qualified to make such diagnosis, and confirmed by abnormal EMG showing typical findings of decrement on repetitive stimulation testing and/or elevated acetylcholine receptor antibodies or (2) submission of sufficient evidence of, and the required findings confirming, such condition.

# 6. Severity/Disability Categories

The compensation level for ANDS will be based on the degree to which the individual is "disabled" by the condition, as the individual's licensed treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individual's ability to perform her vocational, avocational, or usual self-care activities. ("Vocational" means activities associated with work, school, and homemaking. "Avocational" means activities associated with recreation and leisure. "Usual self-care" means activities associated with dressing, feeding, bathing, grooming, and toileting.)

In evaluating the effect of the individual's symptoms, the licensed treating physician will take into account the level of pain and fatigue resulting from the symptoms. The disability percentages

appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the licensed treating physician in the exercise of his or her professional judgment.

#### a. Category A

Death or total disability due to the compensable condition. An individual shall be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only few of the usual duties or activities of vocation or self-care.

#### b. <u>Category B</u>

An individual will be eligible for Category B if she is thirty-five percent (35%) disabled due to the compensable condition. An individual shall be considered thirty-five percent (35%) disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation and self-care, or if she can perform them only with regular or recurring severe pain.

#### c. Category C

An individual will be eligible for Category C if she is twenty percent (20%) disabled due to the compensable condition. An individual shall be considered twenty percent (20%) disabled if she can perform some of her usual activities of vocation, avocation and self-care only with regular or recurring moderate pain.

# D. Mixed Connective Tissue Disease ("MCTD") and Overlap Syndrome

- 1. A diagnosis of Mixed Connective Tissue Disease ("MCTD") shall be based on the presence of clinical symptoms characteristic of two or more rheumatic diseases (SS, SLE, myositis and Rheumatoid Arthritis), accompanied by positive RNP Antibodies. See, e.g., Kelley, et al., Table 63-1, at 1061.
- 2. "Overlap Syndrome" means any one of the following three: (i) diffuse cutaneous scleroderma, (ii) limited cutaneous scleroderma, or (iii) Sine scleroderma, occurring concomitantly with diagnosis of SLE, inflammatory muscle disease or rheumatoid arthritis. See Kelley, et al., supra Table 66-2, at 1114.

3. The application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of MCTD but who nonetheless have an Overlap Syndrome, except that an individual will not be compensated in this category if her symptomology more closely resembles an atypical connective tissue disease condition/atypical rheumatic syndrome/nonspecific autoimmune condition.

#### 4. Severity/Disability Categories

#### a. Category A

Death or total disability resulting from MCTD or Overlap Syndrome. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A of ACTD/ARS.

#### b. Category B

MCTD or Overlap Syndrome, plus major organ involvement or major disease activity including central nervous system, cardiopulmonary, vasculitic or renal involvement or hemolytic anemia (marked) or thrombocytopenic purpura or severe granulocytopenia.

#### c. Category C

Other.

# E. Polymyositis/Dermatomyositis

1. A diagnosis of polymyositis or dermatomyositis shall be made in accordance with diagnostic criteria proposed by Bohan and Peter, i.e., (i) symmetrical proximal muscle weakness, (ii) EMG changes characteristic of myositis including (a) short duration, small or low amplitude polyphasic potential, (b) fibrillation potentials, or (c) bizarre high-frequency repetitive discharges, (iii) elevated serum muscle enzymes (CPK, aldolase, SGOT, SGPT and LDH), (iv) muscle biopsy showing evidence of necrosis of type I and II muscle fibers, areas of degeneration and regeneration of fibers, phagocytosis, and an interstitial or perivascular inflammatory response, (v) dermatologic features including a lilac (heliotrope), erythematous, scaly involvement of the face, neck, shawl area and extensor surfaces of the knees, elbows and medial malleoli and Gottron's papules. A diagnosis of dermatomyositis requires the presence of three of the criteria plus the rash (fifth criterion). A

diagnosis of polymyositis requires the presence of four criteria without the rash. See Kelley, et al., supra at 1163.\_.

2. Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of polymyositis or dermatomyositis but who nonetheless have a polymyositis or dermatomyositis-like disease, except that an individual will not be compensated in this category if her symptomology more closely resembles an ACTD.

#### 3. Severity/Disability Categories

#### a. Category A

Death or total disability resulting from polymyositis or dermatomyositis. An individual will be considered totally disabled based on the functional capacity test set forth for Severity/Disability Category A for ACTD/ARS.

#### b. Category B

Polymyositis or dermatomyositis with associated malignancy and/or respiratory muscle involvement.

# c. Category C

Other, including polymyositis or dermatomyositis with muscle strength of Grade III or less.

# F. Primary Sjorgren's Syndrome

- A clinical diagnosis of Primary Sjogren's Syndrome shall be made in accordance with diagnostic criteria proposed by Fox, et al. See Kelley, et al., Supra Table 55-1, at 932; or Fox, et al. "Primary Sjogren's Syndrome Clinical and Immunopathologic Features," Seminars Arthritis Rheum., 1984; 4:77-105.
- 2. Application of the above diagnostic criteria is not intended to exclude from the compensation program individuals who present clinical symptoms or laboratory findings atypical of Primary Sjogren's Syndrome but who nonetheless have a Primary Sjogren's Syndrome-like disease.

#### 3. Severity/Disability Categories

#### a. Category A

Death or total disability due to the compensable condition. An individual will be considered totally disabled based on the functional capacity test set forth in Severity/Disability Category A for ACTD/ARS.

#### b. Category B

Primary Sjogren's Syndrome with associated central nervous system or severe cardio-pulmonary involvement or Primary Sjogren's Syndrome with pseudolymphoma or associated lymphoma.

c. Category C

Other.

- G. Atypical Connective Tissue Disease ("ACTD"), Atypical Rheumatic Syndrome ("ARS") and Nonspecific Autoimmune Condition ("NAC")
  - 1. This category will provide compensation for individuals experiencing symptoms that are commonly found in autoimmune or rheumatic diseases but which are not otherwise classified in any of the other compensable disease categories. This category does not include individuals who have been diagnosed with classical rheumatoid arthritis in accordance with ACR criteria, but will include individuals diagnosed with undifferentiated connective tissue disease ("UCTD"). However, such inclusion is not intended to exclude from this category persons who do not meet the definition of UCTD, it being intended that individuals not meeting the classic definitions of UCTD will be compensated pursuant to the provisions contained herein relative to ACTD, ARS and NAC.
  - 2. As with other individuals who fit within this disease compensation program, the fact that a breast implant recipient has been in the past misdiagnosed with classic rheumatoid arthritis or the fact that the symptoms of classic rheumatoid arthritis may coexist with other symptoms will not exclude the individual from compensation herein. Persons who meet the criteria below and may have a diagnosis of atypical rheumatoid arthritis will not be excluded from compensation under this category.
  - 3. A diagnosis of ACTD, ARS, or NAC must satisfy one of the sets of criteria below. If the individual's Licensed Medical Specialist

determines that a symptom is clearly and specifically caused by a source other than breast implants, that symptom will not be used in the diagnosis of ACTD or ARS. A symptom that may be caused only in part by a source other than breast implants may be used in the diagnosis or categorization. The relevant groups of symptoms are as follows:

- a. any two of the three signs and symptoms listed in Subparagraph II.G.4.a, below (Group I);
- b. any one of the three signs and symptoms listed in Subparagraph II.G.4.a, below (Group I), plus any one of the ten signs and symptoms listed in Subparagraph II.G.4.b, below (Group II);
- c. any three of the ten signs and symptoms listed in Subparagraph II.G.4.b, below (Group II);
- d. any two of the ten signs and symptoms listed in Subparagraph II.G.4.b, below (Group II), plus any one additional (nonduplicative) sign or symptom from the eighteen listed in Subparagraph II.G.4.c, below (Group III); or
- e. five nonduplicative signs or symptoms listed in Subparagraphs II.G.4.a (Group I), II.G.4.b (Group II) or II.G.4.c (Group III), below;

# 4. Symptom Groupings

- a. Group I Signs and Symptoms
  - (1) Raynaud's phenomenon evidenced by the patient giving a history of two color changes, or visual evidence of vasospasm, or evidence of digital ulceration;
  - (2) polyarthritis, defined as synovial swelling and tenderness in three or more joints lasting greater than six weeks and observed by a physician; and/or
  - (3) Keratoconjunctivitis Sicca: subjective complaints of dry eyes and/or dry mouth, accompanied by any one of the following:
    - lacrimal or salivary enlargement,
    - parotid enlargement,

- abnormal Schirmer test,
- · abnormal Rose-Bengal staining,
- filamentous keratitis,
- abnormal parotid scan or ultrasound,
- abnormal CT or MRI of parotid, or
- abnormal labial salivary biopsy.
- b. Group II Signs and Symptoms
  - (1) Myalgias determined by tenderness on examination;
  - (2) immune mediated skin changes or rash, as follows:
    - changes in texture or rashes that may or may not be characteristic of SLE, SS or dermatomyositis,
    - diffuse petechiae, telangiectasias or livedo reticularis;
  - (3) pulmonary symptoms or abnormalities, which may or may not be characteristic of SLE, SS, or Primary Sjogren's Syndrome, as follows:
    - pleural and/or interstitial lung disease,
    - restrictive lung disease,
    - obstructive lung disease as evidenced by characteristic clinical findings and either characteristic chest X-ray changes, or characteristic pulmonary function test abnormalities in a nonsmoker (e.g., decrease DLCO or abnormal arterial blood gases);
  - (4) pericarditis defined by consistent clinical findings and either EKG or echocardiogram;

- (5) neuropsychiatric symptoms: cognitive dysfunction (memory loss and/or difficulty concentrating) which may be characteristic of SLE or MCTD as determined by a SPECT scan or PET scan or MRI or EEG or neuropsychological testing;
- (6) peripheral neuropathy diagnosed by physical examination showing one or more of the following:
  - loss of sensation to pinprick, vibration, touch or position,
  - tingling, paresthesia or burning pain in the extremities,
  - loss of tendon reflex,
  - proximal or distal muscle weakness (loss of muscle strength in extremities or weakness of ankles, hands or foot drop),
  - signs of dysesthesia, or
  - entrapment neuropathies.
- (7) myositis or myopathy, diagnosed by weakness on physical examination or by muscle strength testing, abnormal CPK or aldolase, abnormal cybex testing, abnormal EMG or abnormal muscle biopsy;
- (8) serologic abnormalities that include any one of the following:
  - ANA greater than or equal to 1:40 (using Hep2),
  - positive ANA profile such as Anti-DNA, SSA, SSB, RNP, SM, Scl-70, centromere, JO-1, PM-Scl or dsDNA (preferable to use ELISA with standard cutoffs),
  - other autoantibodies, including thyroid antibodies, anti-microsomal,

or anti-cardiolipin, or RF (by nephelometry with 40 IU cutoff),

- elevation of immunoglobulin (IgG, IgA, IgM), or
- serologic evidence of inflammation such as elevated ESR, CRP;
- (9) lymphadenopathy (as defined by at least 1 lymph node greater than or equal to 1x1 cm) documented by a physician; or
- (10) dysphagia with positive cine-esophagram, manometry or equivalent imaging.

#### c. Group III Signs and Symptoms

- (1) Documented arthralgia;
- (2) documented Myalgias;
- (3) chronic fatigue ( for more than 6 months);
- (4) documented Lymphadenopathy;
- (5) documented Neurological symptoms including cognitive dysfunction or paresthesia;
- (6) photosensitivity;
- (7) documented Sicca symptoms;
- (8) documented dysphagia;
- (9) documented Alopecia;
- (10) documented sustained balance disturbances;
- (11) documented sleep disturbances;
- (12) documented easy bruisability or bleeding disorder;
- (13) documented chronic cystitis or bladder irritability;
- (14) documented colitis or bowel irritability;

- (15) persistent low grade fever or night sweats;
- (16) mucosal ulcers confirmed by physician;
- (17) burning pain in the chest, breast, arms or axilia, or substantial loss of function in breast due to disfigurement or other complications from implants or explantation; or
- (18) pathological findings of granulomas or siliconomas or chronic inflammatory response or breast infections.

#### 5. Severity/Disability Categories

The compensation level for ACTD/ARS/NAC will be based on the degree to which the individual is "disabled" by the condition, as the individual's licensed treating physician determines in accordance with the following guidelines. The determination of disability under these guidelines will be based on the cumulative effect of the symptoms on the individual's ability to perform her vocational, avocational or usual self-care activities, as defined above. In evaluating the effect of the individual's symptoms, the licensed treating physician will take into account the level of pain and fatigue resulting from the symptoms. The severity/disability percentages appearing below are not intended to be applied with numerical precision, but are, instead, intended to serve as a guideline for the licensed treating physician in the exercise of his or her professional judgment.

#### a. Category A

Death or total disability resulting from the compensable condition. An individual will be considered totally disabled if she demonstrates a functional capacity adequate to consistently perform none or only few of the usual duties or activities of vocation or usual self-care.

# b. Category B

An individual will be eligible for Category B if she is thirty-five percent (35%) disabled due to the compensable condition. An individual shall be considered thirty-five percent (35%) disabled if she demonstrates a loss of functional capacity which renders her unable to perform some of her usual activities of vocation, avocation, and usual self-care, or she can perform them only with regular or recurring severe pain.

#### c. Category C

An individual will be eligible for Category C if she is twenty percent (20%) disabled due to the compensable condition. An individual shall be considered twenty percent (20%) disabled if she can perform some of her usual activities of vocation, avocation and usual self-care only with regular or recurring moderate pain.

#### III. OTHER CONDITIONS

#### A. Rupture

- 1. Rupture" is defined as the failure of the elastomer envelope(s) surrounding a silicone-gel Dow Corning Breast Implant to contain the gel (resulting in contact of the gel with the body), not solely as a result of "gel bleed," but due to a tear or other opening in the envelope occurring after implantation and prior to removal of the Dow Corning Breast Implant(s) where such failure occurs prior to the date eighteen (18) months after the Effective Date Of This Agreement. A diagnosis of Rupture must be made in accordance with the criteria set forth in this Section III.A.
- 2. As set forth in Paragraph 2.3(ii) of Exhibit D to the Agreement, Supporting Medical Documentation for Rupture consists of contemporaneous operative reports, MRI reports and, if available, a pathology report, demonstrating that the claimant has had a Rupture.
- 3. In limited circumstances, such as situations in which the claimant cannot undergo explanation surgery due to medical reasons, the Claims Administrator may accept proof of Rupture consisting of an MRI examination where the MRI is performed by a qualified laboratory and read by a qualified radiologist and the radiologist makes a finding of a definite visible Rupture.
- 4. No Severity/Disability Categories are applicable to Rupture.

#### B. Explantation

- 1. A diagnosis of and compensation for, Explantation must be made in accordance with the criteria set forth in this Section III.B.
- 2. "Explantation" means the surgical removal for any of the medical reasons listed below of one or more Dow Corning Breast Implants prior to the date eighteen (18) months after the Effective Date of this Agreement but "Explanation" does not include either any such removal that occurred after January 1, 1992 if the claimant

whose Dow Corning Breast Implants were removed subsequently was implanted with any other silicone-gel Breast Implant, or any removal of Breast Implant(s) for purely cosmetic reasons.

- 3. The medical reasons for Explanation must have been contemporaneously documented in the claimant's medical records and are limited to the following:
  - a. pain or tenderness,
  - b. deformity,
  - c. ancillary nodes,
  - d. recurrent fibrous shell necessitating manual or operative Rupture, and/or
  - e. Rupture, as described in Paragraph III.A, above.
- 4. As set forth in Paragraph 2.3(i) of Exhibit D of the Agreement, Supporting Medical Documentation for Explantation consists of contemporaneous medical records of the Explantation procedure providing the date of the Explantation procedure. Such medical records shall include the surgical report, contemporaneous hospital records including the hospital pathology report, the explanting surgeon's contemporaneous office notes and/or the bill from the explanting surgeon or private clinic.
- 5. No Severity/Disability Categories are applicable to Explantation.