Patient Report

International Scientific Instrument Technology Workshop
Instrument Technology Reseach Center
National Applied Reserch Laboratories

Instructions: This report must be completed by a registered medical practitioner after clinical and laboratory examination including HIV, VDRL, TPHA and TB tests. The training institution (ISIT Workshop, ITRC) will require the participants to undergo a further HIV test upon their arrival in Taiwan. Those who being confirmed with positive result on HIV test will be rejected and sent back home immediately.

Medical Report

Date:
(DD/MM/YYYY)

1. Name:
2. Address:
3. Sex: □ Male □ Female
4. Marital State: □Single □ Married
5. Blood Type:
6. Please examine the following medical conditions:
   a. HIV Test:
   b. TB Test:
   c. Heart Disease:
   d. High Blood Pressure
   e. Malaria:
   f. Liver Function:
   g. VDRL Test:
   h. TPHA Test:

In the opinion of the examining physician, is the candidate fit for this fellowship?
Seal of Hospital or Clinic:
Name of Doctor: Signature:
(Upon signing this report, the examining doctor hereby certifies the above examinations are true conditions of the examinee)
Address: Fax: Tel:

Patient Prescription

Form # MDIR03, for use by medical device sponsors / manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR03

Mfr report # *

TGA DIR #

I- Administrative Information *Mandatory
Report Type (select one)
Initial

Follow-Up

Final

Trend

Report Category
S Pblc Hlth Threat

Death/Serious Injury

Other

A) Date of this report (dd-mm-yyyy)

B) Date of adverse event (dd-mm-yyyy)

C) Date mfr aware (dd-mm-yyyy)

D) Date of next report (max 30 days from A)

Person (authorised representative) Submitting This Report
Name

Company

Address

Tel.

Fax

E-mail

Identity of all other Regulatory Authorities, Notified Bodies, etc., where this report was also sent.

II- Clinical Event Information *Mandatory
Description of event or problem
If the device is an implantable device indicate both implant and explant dates below
Implant Date:

Explant Date:

III- Healthcare Facility Information *Mandatory
Name

Address

Tel

Fax

E-mail

Contact name at site of event

IV- Device Information Primary Device *Mandatory
Generic Device Information
Device ARTG # *

GMDN Code

GMDN Code Text (eg catheters, central venous, peripherally inserted)

Specific Device Information
Brand Name *

Model # *

Catalogue #

Ser. or Lot #’s

Mfr. Name*

Contact Name *

Address *

Tel *

Fax

E-mail *

ARTG Mfr. # *

Operator of Device at Time of Event (select one)
HC Prof’nal

Other Caregiver

Patient

N/A

Usage of Device*
Single Use

Reuse of Single Use

Reuse of Reusable

Re-serviced/Refurbished

Device Disposition/Current Location *

V- Results of Mfr's Investigation *Mandatory
Manufacturers Device Analysis Results
(Specify, for this event, details of investigation methods, results, and conclusions)

Remedial Action/Corrective Action/Preventive Action
(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

VI- Patient Information *Mandatory as marked below
Age (yrs, mths)

M/F

Wt. (kg)

Patient Focused Resolution of Events and Outcomes
Corrective action taken relevant to the care of the patient:

Patient history (co-morbidities & medication):

* Patient outcome:

* List of other devices involved in the event:
if other implants involved – list brand, model & ARTG #

VII- Other Reporting Information *Mandatory
Mfr/Sponsor aware of other similar events? (*number or *rate)

Countries where these similar adverse events occurred:

Additional Comments

Submitting this report:
By mail: Reply Paid 100
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606
By fax: +61 (0) 2 6232 8555
By e-mail: iris@tga.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Patient History

The purpose of the questions in this form is to gather information concerning your health and physical condition, both now and in the past. (POST Rule 464-3-.02 requires that officers be found, after examination by a licensed physician or surgeon, to be free from any physical, emotional, or mental conditions which might adversely affect his/her exercising the powers or duties of a peace officer.) This information will be used only to determine whether you can safely complete the required training and safely perform such duties. Please answer all of the following questions as fully and completely as you can. If you don't understand a question, or are unsure of how to answer it, leave it blank and request assistance from your hiring agency or your physician. Most individuals will have some "yes" answers, and it is not necessarily a disqualification. THIS FORM IS FOR THE PHYSICIAN ONLY AND IS TO BE GIVEN BY THE CANDIDATE TO THE PHYSICIAN AT THE EXAM.

Last Name

First Name

Middle Name

DATE OF BIRTH (mmddyyyy)
Check if applies:
Jr. Sr.
III IV
Other:_____
MAIDEN NAME

SEX: Male
Female
Social Security Number:

The job/position that candidate is applying for is:

AGENCY APPLYING WITH

AGENCY PHONE#
(AREA CODE) - NUMBER
( )- -
NAME OF AGENCY CONTACT(Person Processing Application w/in Agency)

CONTACT PHONE#
(AREA CODE) - NUMBER
( )- -
ATTESTATION: I certify under penalty of perjury, that the information given by me is true to the best of my knowledge and belief. I agree and understand that any misstatements of material facts may cause forfeiture on my part of all right to employment as a peace officer in the State of Georgia, may result in dismissal after appointment; or may result in loss of entitlement to disability

retirement benefits. My signature also indicates that I understand all of the questions on this medical history form.

CANDIDATE'S SIGNATURE:
_____DATE:_____

INDIVIDUAL HISTORY - TO BE COMPLETED BY THE CANDIDATE (Use Ink Only)
MEDICAL CONDITIONS INSTRUCTIONS: Do you have or have you ever had any of the following: (Check every item. If "YES", give year of most recent medical occurrence & explain on page 3.)
Health Condition
Yes
Year
No
Health Condition
Yes
Year
No

CARDIOVASCULAR SYSTEM (HEART & BLOOD VESSELS)

SKIN

1. Heart Attack

12. Rash

2. Hardening of the arteries (Arteriosclerosis)

13. Hives

3. High or low blood pressure

14. Moles that bleed/get larger

4. Heart Murmur

15. Change in color of skin (other than suntan)

5. Palpitations or irregular heart beat

16. Frequent boils/abscesses

6. Episodes of chest pains, tightness, discomfort

17. Trouble with fingernails

7. Shortness of breath

18. Small itching blisters on the side of fingers or palms

8. Varicose veins

19. Sores that do not heal

9. Swelling of ankles, feet or legs (edema)

20. Other skin conditions

10. Leg pains, cramps

11. Other cardiac conditions

Health Condition
Yes
Year
No
Health Condition
Yes
Year
No

EYES & VISION

HEAD, NOSE, MOUTH & THROAT

21. Glaucoma

51.Persistent severe headaches

22. Cataract

52. Frequent nose bleeds

23. Eye irritations (itching or burning)

53. Frequent nasal congestion

24. Eye infection

54. Persistent or severe sinus condition

25. Defective vision

55. Bleeding gums

26. Color blindness

56. Persistent or severe dental condition

27. Injury to eye

57. Hoarse when don't have cold

28. Eye surgery

58. Difficulty swallowing

29. Double vision

59. Persistent sore throat

30. Glasses

60. Loss of taste or smell

31. Contact lenses

61. Head injury

EARS & HEARING

62. Other head, nose, mouth, or throat conditions

32. Hearing difficulties

BLOOD/LYMPH (HEMATOLOGIC) SYSTEMS

33. Use hearing aid

63. Anemia

34. Ringing in the ears (tinnitus)

64. Bleeding disorder

35. Perforated ear drum

65. Sickle cell disease or trait

36. Persistent or severe ear infection

66. Phlebitis/blood clot

37. Other ear or hearing conditions

67. Blood transfusion

RESPIRATORY SYSTEM (LUNGS & BREATHING)

68. Chills, fever, night sweats

38. Persistent or severe colds

69. Lymph node or persistent glandular swelling

39. Persistent or severe cough

70. Other conditions of blood or lymph

40. Coughing blood

GASTROINTESTINAL SYSTEM (STOMACH & INTESTINES)

41. Asthma or breathing difficulty

71. Persistent or severe nausea or indigestion

42. Emphysema

72. Persistent or severe stomach pain

43. Pneumonia

73. Vomiting blood

44. Tuberculosis

74. Persistent or severe vomiting

45. Other lung or breathing condition

75. Hernia (rupture)

LIVER, SPLEEN, & GALLBLADDER

76. Stomach or duodenal ulcer

46. Cirrhosis

77. Colitis

47. Hepatitis

78. Hemorrhoids or piles

48. Yellow jaundice

79. Change in bowel habits

49. Gallstones

80. Block stool or blood in stool

50. Other conditions of liver, spleen, or gallbladder

81. Persistent or severe constipation