Serious Adverse Event Form

 **CROES**	**ID** **Site No.**		**Investigator**
	Subject No.		**Nanoknife for the treatment of prostate cancer**
	Subject's initials		**Protocol ID: NL50791.018.14**

SERIOUS ADVERSE EVENT REPORT

1. REPORT TYPE: ☐ Initial ☐ Follow-up | 2. Country: | 3. Hospital:

I. ADVERSE EVENT INFORMATION

4. DATE OF BIRTH	5. AGE	6.RACE	7.SEX	8. HEIGHT	9. WEIGHT	10. ONSET OF FIRST SIGN/SYMPTOM OF SAE
day month year	yrs./mo.	☐ Caucasian ☐ Oriental ☐ Black ☐ Other	☐ Male	cm	kg	day month year

11. SERIOUS ADVERSE EVENT(S) IN MEDICAL TERMS (diagnosis, if possible)

Case description of the above SAE (include related signs/symptoms, treatment, course/outcome and suspected cause of the SAE) (continue on P.3 if more space is required):

EXPEDITED REPORTING CRITERIA

12. CHECK ALL APPROPRIATE TO EVENT

☐ Patient died — day month year

☐ Involved or prolonged inpatient hospitalization

☐ Results in persistent or significant disability / incapacity

☐ Life-threatening

Other Seriousness Criteria:

☐ Other significant medical events

II. HISTORY

13. PATIENT'S PAST MEDICAL HISTORY (e.g. co-existing medical conditions such as disease, allergies, similar experiences)

please FAX form to 0031205669585 or EMAIL form to info@croesoffice.org

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14. CONCOMITANT DRUGS RELEVANT TO THE SAE (exclude therapy to treat SAE)

DRUG NAME(S)	DOSE ROUTE	UNIT SCHEDULE	DATE STARTED day month year	CONT. 0=No 1=Yes	DATE DISCONTINUED day month year	REASON FOR USE

15. COMMENTS (If adverse event is considered to be caused by a concomitant medication, please note it here)

16. ACTION TAKEN (mark all as appropriate)

☐ No Action Taken ☐ Hospitalization/prolonged hospitalization ☐

☐ Concomitant medication taken ☐ ☐

☐ Non-drug therapy given ☐

17. TEST / LABORATORY FINDINGS (enter only those findings necessary for SAE diagnosis or course description)

TEST/ LAB NAME	UNIT	DATE day month year	VALUE	DATE day month year	VALUE	DATE day month year	VALUE

18. COMMENTS ON TEST/LABORATORY FINDINGS

19. OUTCOME OF THE PATIENT/SAE

☐ Completely Recovered Date of recovery: day month year ☐ Condition still present and unchanged

☐ Recovered with sequelae ☐ Condition deteriorated

☐ Condition improving ☐ Death Autopsy: ☐ No ☐ Yes

20. ASSESSMENT OF CAUSALITY

Relationship to study protocol *(tick all that apply)* ☐ Not suspected ☐ Suspected

V. INFORMATION SOURCE

21. NAME, ADDRESS AND TELEPHONE NUMBER OF INVESTIGATOR	32. REPORTING DATE BY INVESTIGATOR/PERSON REPORTING EVENT
Signature:	day month year

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SERIOUS ADVERSE EVENT REPORT

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FOR ADDITIONAL INFORMATION:

V. INFORMATION SOURCE

22. NAME, ADDRESS AND TELEPHONE NUMBER OF INVESTIGATOR	23. REPORTING DATE BY INVESTIGATOR/PERSON REPORTING EVENT
Signature:	day month year

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