

Optical Tissue Stylet Vascular access study – Case Report Form v1 v1.0

Date: ex / ur / 2011

signed informed consent? yes: ☒ no: ☐

Subjects date of birth: 00/07/1959

older than 18 y: yes: ☒ no: ☐

Subjects height: 1.64

Subject s ASA status 1? yes: ☒ no: ☐

Subjects weight: 75

Coagulation deficiencies? yes: ☐ no: ☒

Subjects sex: female: ☒ male: ☐

Subject number in clinical study:

R1014

Optical Tissue Stylet – Vascular Access study
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Disposable nr optical tissue stylet:

8013112 000 000 1

Position nr: 1

Position identified as: subcl

Optical spectra collected:

time: 14:01
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: Rin

comments: _____

Vascular puncture?

☐ No

☐ Yes,

vessel diameter: _____ mm

☐ Aspiration performed:

☐ positive

☐ negative

comments: _____

Position nr: 2

Position identified as: vein Rin

Aiming for vascular puncture:
(envelope content) ☒ yes

☐ no

Optical spectra collected:

time: 11:02
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: Rin

comments: _____

Vascular puncture?

☐ No

☒ Yes,

vessel diameter: 3 mm

☒ Aspiration performed:

☒ positive

☐ negative

comments: steward premed 5ml

Subject number in clinical study:

Rin

Optical Tissue Stylet – Vascular Access study
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Disposable nr optical tissue stylet:

8013112 000 0001

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 9

Nr. first file: 1 time: 10:59

Nr. last file: 10 time: 10:59

Comments: /

Offline analysis performed on (date): 30-8-2011

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Position nr: 2

Optical spectra collected:

Experiment nr.: 20

Session number: 9

Nr. first file: 11 time: 11:01

Nr. last file: 20 time: 11:01

Comments: _____

Offline analysis performed on (date): 30-8-2011

Vascular puncture?
(from off line analysis)

☐ No

☒ Yes,

Comments: Large variation in B2 value:
spectrum 11-15: B2=13 to 30
spectrum 16-20: B2=508 to 2907
as if two sets measured at different
locations

number in clinical study:

2,014

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Disposable nr optical tissue stylet:

8013112 003 0001

Tests for the study completed?

yes: ☒ no: ☐

If not: describe reason

(Serious) Adverse Events?

yes: ☐ no: ☒

If yes: describe event, and follow up

optical tissue stylet disposed:

yes: ☒ no: ☐

if not describe reason:

Remarks:

Steward has been making
LU

Subject number in clinical study:

R, 014

OTS VA

Measurements to be performed:

1. Non-vascular – probably in subcutaneous fat
2. Vascular

Subject nr in study: _____

R19