

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

Date: 5-7-2011

Subjects date of birth: 21-04-1990

Subjects height: 1.90

Subjects weight: 82

Subjects sex: female: ☐ male: ☒

signed informed consent? yes: ☒ no: ☐

older than 18 y: yes: ☒ no: ☐

Subject s ASA status 1? yes: ☒ no: ☐

Coagulation deficiencies? yes: ☐ no: ☒

Subject number in clinical study:

R, 10

Optical Tissue Stylet – Vascular Access study
Case Report Form v0.2 – June 2011

Disposable nr optical tissue stylet:

8013112 000012

Position nr: 1

Position identified as: Subcut

Optical spectra collected:

time: 10:28
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: _____

comments: _____

Vascular puncture?

☒ No

☐ Yes,

vessel diameter: _____ mm

☐ Aspiration performed: ☐ positive

☐ negative

comments: _____

Position nr: 2

Position identified as: Subcut

Aiming for vascular puncture:
(envelope content) ☒ yes

☐ no

Optical spectra collected:

time: 10:35
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R10

comments: _____

Vascular puncture?

☒ No

☐ Yes,

vessel diameter: 2 mm

☐ Aspiration performed: ☐ positive

☒ negative

comments: _____

Subject number in clinical study:

R1 ~~001~~ 10

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

8013112 0000012

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 5

Nr. first file: 1 time: 10:22

Nr. last file: 10 time: 10:33

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: 5

Nr. first file: 11 time: 10:24

Nr. last file: 20 time: 10:25

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

R, 10

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Disposable nr optical tissue stylet:

8013112 - 000 0012

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:

bedrocking 10 → 66ml subcut.

Subject number in clinical study:

R.10

OTS VA

Measurements to be performed:

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

Subject nr in study:

Ry C10