

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

Date: 5-7-2011

Subjects date of birth: 15-10-'59

Subjects height: 1.59 m

Subjects weight: 82 kg

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, 08

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

Disposable nr optical tissue stylet:

8013112 000 0004

Position nr: 1

Position identified as: Subcut

Optical spectra collected:

time: 10¹⁰
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: ☐ yes

☒ no

Optical spectra collected:

time: 10¹²
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: _____

comments: _____

Vascular puncture?

☒ No

☐ Yes, vessel diameter: _____ mm

☐ Aspiration performed: ☐ positive ☒ negative

comments: _____

Subject number in clinical study:

R108

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

Disposable nr optical tissue stylet:

8013112 8000004

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 3

Nr. first file: 1 time: 10:06

Nr. last file: 11 time: 10:07

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: 3

Nr. first file: 12 time: 10:08

Nr. last file: 21 time: 10:08

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

R,08

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Disposable nr optical tissue stylet:

8 013112 000 0004

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:

Subject number in clinical study:

R,08

Measurements to be performed:

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

Subject nr in study: 108