

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

Date: 28/07/2011

signed informed consent? yes: ☒ no: ☐

Subjects date of birth: 22/01/1986

older than 18 y: yes: ☒ no: ☐

Subjects height: 1.07

Subject s ASA status 1? yes: ☒ no: ☐

Subjects weight: 104

Coagulation deficiencies? yes: ☐ no: ☒

Subjects sex: female: ☐ male: ☒

Subject number in clinical study:

R, 18

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

Disposable nr optical tissue stylet:

8013112 0000006

Position nr: 1

Position identified as: subcut

Optical spectra collected:

time: 1126
comments: _____

Position confirmed by:



ultrasound

ID confirmation image: R. 10

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: 1127
comments: _____

Position confirmed by:



ultrasound

ID confirmation image: R. 10

comments: _____

Vascular puncture?



No



Yes,

vessel diameter:

mm



Aspiration performed:



positive



negative

comments: gl

Subject number in clinical study:

R. 18

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

Disposable nr optical tissue stylet:

8013112 0000006

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 12

Nr. first file: 6

time: ~~11:26~~ 11:26

Nr. last file: 15

time: 11:26

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: 12

Nr. first file: 16

time: 11:27

Nr. last file: 25

time: 11:28

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

R18

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

Disposable nr optical tissue stylet:

8013112 000 000 1

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:

gh

Subject number in clinical study:

R, 18

Measurements to be performed:

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

Subject nr in study:

12

12