

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

Date: 05-07-11

signed informed consent? yes: ☒ no: ☐

Subjects date of birth: 26-08-1971

older than 18 y: yes: ☒ no: ☐

Subjects height: 175

Subject s ASA status 1? yes: ☒ no: ☐

Subjects weight: 101.00

Coagulation deficiencies? yes: ☒ no: ☒

Subjects sex: female: ☒ male: ☒

Subject number in clinical study:

R, 015

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

Disposable nr optical tissue stylet:

8013112 000 0002

Position nr: 1

Position identified as: SSJ

Optical spectra collected:

time: 11 03
comments: _____

Position confirmed by:



ultrasound

ID confirmation image: R15

comments: _____

Vascular puncture?



No



Yes,

vessel diameter:

mm



Aspiration performed:



positive



negative

comments: _____

Position nr: 2

Position identified as: SSJ

Aiming for vascular puncture:
(envelope content)

☐ yes

☒ no

Optical spectra collected:

time: 11 03
comments: _____

Position confirmed by:



ultrasound

ID confirmation image: R15

comments: _____

Vascular puncture?



No



Yes,

vessel diameter:

mm



Aspiration performed:



positive



negative

comments: _____

Subject number in clinical study:

R1015

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

Disposable nr optical tissue stylet:

8013112 0000002

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 10

Nr. first file: 1 time: 11:09

Nr. last file: 10 time: 11:10

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: 10

Nr. first file: 11 time: 11:19

Nr. last file: 20 time: 11:11

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

R1015

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

Disposable nr optical tissue stylet:

8013112 000 0002

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.015

Measurements to be performed:

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

Subject nr in study: 215