

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

Date: <u>5-7-2011</u>	signed informed consent? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects date of birth: <u>8/8/77</u>	older than 18 y: yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects height: <u>1.65</u>	Subject s ASA status 1? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects weight: <u>72</u>	Coagulation deficiencies? yes: <input type="checkbox"/> no: <input checked="" type="checkbox"/>
Subjects sex: female: <input checked="" type="checkbox"/> male: <input type="checkbox"/>	

Subject number in clinical study:

R109

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

Disposable nr optical tissue stylet:

8013112 00000025

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 4

Nr. first file: 1 time: 10:13

Nr. last file: 10 time: 10:14

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: 4

Nr. first file: 11 time: 10:15

Nr. last file: 20 time: 10:15

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

R.09

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

Disposable nr optical tissue stylet:

8013112 000005

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:

gs.

Subject number in clinical study:

R.09

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

Disposable nr optical tissue stylet:

8013112 0000005

Position nr: 1

Position identified as: subcl

Optical spectra collected:

time: 1013
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: subcl

Aiming for vascular puncture:
(envelope content) ☐ yes ☒ no

Optical spectra collected:

time: 1013
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:

R.09

Measurements to be performed:

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

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