

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

Date: <u>05/07/2011</u>	signed informed consent? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects date of birth: <u>11/11/1976</u>	older than 18 y: yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects height: <u>179</u>	Subject s ASA status 1? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects weight: <u>65</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:

R, 13

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

Disposable nr optical tissue stylet:

8013112 0000003

Position nr: 1

Position identified as: subcl.

Optical spectra collected:

time: 1:55
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: vein.

Aiming for vascular puncture:
(envelope content)



yes



no

Optical spectra collected:

time: _____
comments: _____

Position confirmed by:



ultrasound

ID confirmation image: 2.0m.

comments: doubtful

Vascular puncture?



No



Yes,

vessel diameter:

mm



Aspiration performed:



positive



negative

comments: _____

Subject number in clinical study:

R, 13

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Page for hospital only !
(single blind study)

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Disposable nr optical tissue stylet:

8013112 0000003

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 8

Nr. first file: 1 time: 10:49

Nr. last file: 10 time: 10:49

Comments: 10ge verstrooing

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: 8

Nr. first file: 12 time: 10:51

Nr. last file: 21 time: 10:52

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

R₁ 13

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Disposable nr optical tissue stylet:

8013112 000 0003

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:

P/S

Subject number in clinical study:

R, 13

OTS VA

Measurements to be performed:

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

Subject nr in study: 2, 13