

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

Date: <u>08/07/2011</u>	signed informed consent? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects date of birth: <u>17/12/1978</u>	older than 18 y: yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects height: <u>175</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:

R12

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

Disposable nr optical tissue stylet:

8013112 000008

Position nr: 1

Position identified as: sub

Optical spectra collected:

time: 1045
comments: _____

Position confirmed by:

☒ ultrasound

ID confirmation image: R.12

comments: _____

Vascular puncture?

☐ No

☐ Yes,

vessel diameter: _____ mm

☐ Aspiration performed:

☐ positive

☐ negative

comments: _____

Position nr: 2

Position identified as: ~~sub~~ venous

Aiming for vascular puncture:
(envelope content)

☒ yes

☐ no

Optical spectra collected:

time: 1046
comments: _____

Position confirmed by:

☒ ultrasound

ID confirmation image: R.12

comments: _____

Vascular puncture?

☐ No

☒ Yes,

vessel diameter: / mm

☐ Aspiration performed:

☒ positive

☐ negative

comments: _____

Subject number in clinical study:

R.12

Optical Tissue Stylet – Vascular Access study
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Disposable nr optical tissue stylet:

8013112 0000008

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 7

Nr. first file: 1 time: 10:41

Nr. last file: 10 time: 10:42

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: 7

Nr. first file: 11 time: 10:43

Nr. last file: 20 time: 10:44

Comments: _____

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

Vascular puncture?
(from off line analysis)

☐ No

☒ Yes,

Comments: _____

Subject number in clinical study:

R12

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Disposable nr optical tissue stylet:

801312 000 0008

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:

8

Subject number in clinical study:

R, 12

OTS VA

Measurements to be performed:

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

Subject nr in study: 12, 12