

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

Date: <u>30/06/2011</u>	signed informed consent? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects date of birth: <u>12/03/1965</u>	older than 18 y: yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects height: <u>190</u>	Subject s ASA status 1? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects weight: <u>87</u>	Coagulation deficiencies? yes: <input type="checkbox"/> no: <input checked="" type="checkbox"/>
Subjects sex: female: <input type="checkbox"/> male: <input checked="" type="checkbox"/>	

Subject number in clinical study:

R101

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

Disposable nr optical tissue stylet:

0011113 0000011

Position nr: 1

Position identified as: subcut.

Optical spectra collected:

time: 10:15

comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: Rei

comments: _____

Vascular puncture?

☒ No

☒ Yes,

vessel diameter: 1 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: 10:15

comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: Rei

comments: _____

Vascular puncture?

☐ No

☒ Yes,

vessel diameter: 2 mm

☒

Aspiration performed:

☒ positive

☐ negative

comments: _____

Subject number in clinical study:

Rei

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

00 11113 0000011

Position nr: 1

Optical spectra collected:

Experiment nr.: 17

Session number: 2

Nr. first file: 3 time: 10.15

Nr. last file: 13 time: 10.16

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.: _____

Session number: _____

Nr. first file: 14 time: 10.18

Nr. last file: 20 time: 10.19

Comments: _____

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

Vascular puncture?
(from off line analysis)

☐ No

☒ Yes,

Comments: _____

Subject number in clinical study:

R101

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Disposable nr optical tissue stylet:

no 11113 0000011

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:

Unremarkable

Subject number in clinical study:

R01

OTS VA

Measurements to be performed:

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

Subject nr in study:

R. 01