

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>25/10/1959</u>	older than 18 y: yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects height: <u>174</u>	Subject s ASA status 1? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects weight: <u>75</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. 03

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

Disposable nr optical tissue stylet:

801113 0000008

Position nr: 1

Position identified as: R, 03

Optical spectra collected:

time: 1030
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R, 03

comments: _____

Vascular puncture?

☒ No

☐ Yes,

vessel diameter: _____ mm

☐ Aspiration performed:

☐ positive

☐ negative

comments: _____

Position nr: 2

Position identified as: Subat.

Aiming for vascular puncture:
(envelope content) ☐ yes

☒ no

Optical spectra collected:

time: 1030
comments: _____

Position confirmed by: ☐ ultrasound

ID confirmation image: R, 03

comments: _____

Vascular puncture?

☒ No

☐ Yes,

vessel diameter: _____ mm

☐ Aspiration performed:

☐ positive

☒ negative

comments: _____

Subject number in clinical study:

R, 03

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Page for hospital only !
(single blind study)

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

801113 00000018

Position nr: 1

Optical spectra collected:

Experiment nr.: 17

Session number: 4

Nr. first file: 1

time: 10:39

Nr. last file: 10

time: 10:40

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: 11

time: 10:40

Nr. last file: 20

time: 10:41

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

12,03

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Disposable nr optical tissue stylet:

801113 000 000 8

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:

R03

OTS VA

Measurements to be performed:

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

Subject nr in study: 2, 03