

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

Date: 30/06/2011

Subjects date of birth: 23/12/1975

Subjects height: 165

Subjects weight: 64

Subjects sex: female: ☒ male: ☐

signed informed consent? yes: ☒ no: ☐

older than 18 y: yes: ☒ no: ☐

Subject s ASA status 1? yes: ☒ no: ☐

Coagulation deficiencies? yes: ☐ no: ☒

Subject number in clinical study:

2, 02

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

Disposable nr optical tissue stylet:

NO 11118 0000006

Position nr: 1

Position identified as: Subcut.

Optical spectra collected:

time: 1029
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R, 02

comments: _____

Vascular puncture?

☒ No

☐ Yes,

vessel diameter:

mm

☐ Aspiration performed:

☐ positive

☐ negative

comments: _____

Position nr: 2

Position identified as: Subcut.

Aiming for vascular puncture:
(envelope content) ☐ yes

☒ no

Optical spectra collected:

time: 1030
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R, 02

comments: _____

Vascular puncture?

☒ No

☐ Yes,

vessel diameter:

mm

☐ Aspiration performed:

☐ positive

☒ negative

comments: _____

Subject number in clinical study:

R, 02

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

8011113 0000000

Position nr: 1

Optical spectra collected:

Experiment nr.: 17

Session number: 3

Nr. first file: 1 time: 10:27

Nr. last file: 10 time: 10:28

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.: 17

Session number: 3

Nr. first file: 11 time: 10:29

Nr. last file: 20 time: 10:30

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No

☐ Yes,

Comments: _____

Subject number in clinical study:

R102

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

81113 0000006

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:

R1 02

OTS VA

Measurements to be performed:

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

Subject nr in study: R, 02