

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

Date: 30-6-12-11

signed informed consent? yes: ☒ no: ☐

Subjects date of birth: 06/10/1980

older than 18 y: yes: ☒ no: ☐

Subjects height: 171

Subject s ASA status 1? yes: ☒ no: ☐

Subjects weight: 62

Coagulation deficiencies? yes: ☐ no: ☒

Subjects sex: female: ☒ male: ☐

Subject number in clinical study:

R.06

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

Disposable nr optical tissue stylet:

801113 0000003

Position nr: 1

Position identified as: Subcut.

Optical spectra collected:

time: 11:14
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R, 06

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: 11:12
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R, 06

comments: _____

Vascular puncture?

☐ No

☒ Yes,

vessel diameter: 1 1/2 mm

☒ Aspiration performed:

☒ positive

☐ negative

comments: _____

Subject number in clinical study:

R, 06

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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:

8011113 000 0003

Position nr: 1

Optical spectra collected:

Experiment nr.: 17

Session number: 9

Nr. first file: 1 time: 11:14

Nr. last file: 10 time: 11:14

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: 9

Nr. first file: 11 time: 11:17

Nr. last file: 20 time: 11:18

Comments: _____

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

Vascular puncture?
(from off line analysis)

☐ No

☒ Yes,

Comments: _____

Subject number in clinical study:

R106

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

801113 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:

no push

Subject number in clinical study:

R106

Measurements to be performed:

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

Subject nr in study: R, 06