

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

Date: 5-7-2011

Subjects date of birth: 4-2-54

Subjects height: 16.2

Subjects weight: 65

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:

R, 016

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

Disposable nr optical tissue stylet:

8013112 000 0007

Position nr: 1

Position identified as: scd4

Optical spectra collected:

time: 11:16
comments: _____

Position confirmed by:

☐ ultrasound

ID confirmation image: R. 16

comments: _____

Vascular puncture?

☒ No

☐ Yes, vessel diameter: _____ mm

☐ Aspiration performed: ☐ positive ☐ negative

comments: _____

Position nr: 2

Position identified as: velu

Aiming for vascular puncture:
(envelope content) ☐ yes ☐ no

Optical spectra collected:

time: 11:17
comments: _____

Position confirmed by:

☒ ultrasound

ID confirmation image: R. 16

comments: _____

Vascular puncture?

☐ No

☒ Yes, vessel diameter: 1,5 mm

☒ Aspiration performed: ☒ positive ☐ negative

comments: _____

Subject number in clinical study:

R. 016

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

8013112 2000007

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 11

Nr. first file: 1 time: 11:16

Nr. last file: 10 time: 11:17

Comments: lage verstraling

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: 11

Nr. first file: 11 time: 11:18

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:

R016

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Disposable nr optical tissue stylet:

8013112 000 0007

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:

gs

Subject number in clinical study:

R, 016

OTS VA

Measurements to be performed:

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

Subject nr in study: 2, 16