

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

Date: 5-7-'11

signed informed consent? yes: ☒ no: ☐

Subjects date of birth: 15-08-'80

older than 18 y: yes: ☒ no: ☐

Subjects height: 182

Subject s ASA status 1? yes: ☐ no: ☐

Subjects weight: 70

Coagulation deficiencies? yes: ☐ no: ☐

Subjects sex: female: ☐ male: ☒

Subject number in clinical study:

R, 19

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

Disposable nr optical tissue stylet:

0013111 00000-8

Position nr: 1

Position identified as: Scal

Optical spectra collected:

time: 1144
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R19

comments: _____

Vascular puncture?

☒ No

☐ Yes,

vessel diameter: _____ mm

☐ Aspiration performed:

☐ positive

☐ negative

comments: _____

Position nr: 2

Position identified as: Venous

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

Optical spectra collected:

time: 1145
comments: _____

Position confirmed by: ☒ ultrasound

ID confirmation image: R19

comments: clust / vessel wall?

Vascular puncture?

☒ No

☐ Yes,

vessel diameter: 2 mm

☐ Aspiration performed:

☐ positive

☒ negative

comments: _____

Subject number in clinical study:

R19

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

801311 000 0008

Position nr: 1

Optical spectra collected:

Experiment nr.: 20
Session number: 14
Nr. first file: 1 time: 11:44
Nr. last file: 10 time: 11:45

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.: 20
Session number: 14
Nr. first file: 11 time: 11:46
Nr. last file: 20 time: 11:46

Comments: _____

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

Vascular puncture?
(from off line analysis)

☒ No
☐ Yes,

Comments: _____

Subject number in clinical study:

R. 19

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Disposable nr optical tissue stylet:

801311 0000008

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:

double sensors to right, e-l for apical @
Uga

Subject number in clinical study:

R. 19

OTS VA

Measurements to be performed:

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

Subject nr in study: 2, 19