

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

Date: 5-7-2011

Subjects date of birth: 05-11-1954

Subjects height: 185

Subjects weight: 112

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:

21017

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

Disposable nr optical tissue stylet:

8013112 0000011

Position nr: 1

Position identified as: Subcut

Optical spectra collected:

time: 11:36  
comments: \_\_\_\_\_

Position confirmed by:

☒ ultrasound

ID confirmation image: R17

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: 11:36  
comments: \_\_\_\_\_

Position confirmed by:

☒ ultrasound

ID confirmation image: R17

comments: \_\_\_\_\_

Vascular puncture?

☒ No

☐ Yes, vessel diameter: 2 mm

☐ Aspiration performed: ☐ positive ☐ negative

comments: q3

Subject number in clinical study:

R.017

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

8013112 000 0011

Position nr: 1

Optical spectra collected:

Experiment nr.: 20

Session number: 13

Nr. first file: 1 time: 11:35

Nr. last file: 10 time: 11:36

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: 13

Nr. first file: 11 time: 11:36

Nr. last file: 20 time: 11:37

Comments: \_\_\_\_\_

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

Vascular puncture?  
(from off line analysis)

☒ No

☐ Yes,

Comments: \_\_\_\_\_

Subject number in clinical study:

R, 017

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Disposable nr optical tissue stylet:

801 3112 000 6011

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:

JS

Subject number in clinical study:

R, 017

117

OTS VA

Measurements to be performed:

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

Subject nr in study: 117