

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

Date: <u>30/06</u>	signed informed consent? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects date of birth: <u>24/02/1951</u>	older than 18 y: yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects height: <u>170</u>	Subject s ASA status 1? yes: <input checked="" type="checkbox"/> no: <input type="checkbox"/>
Subjects weight: <u>72</u>	Coagulation deficiencies? yes: <input type="checkbox"/> no: <input checked="" type="checkbox"/>
Subjects sex: female: <input checked="" type="checkbox"/> male: <input type="checkbox"/>	

Subject number in clinical study:

R104

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

Disposable nr optical tissue stylet:

801113 000 000 2

Position nr: 1

Position identified as: Subcl.

Optical spectra collected:

time: 10:50

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

Position confirmed by: ☒ ultrasound

ID confirmation image: R104

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: 10:51

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

Position confirmed by: ☒ ultrasound

ID confirmation image: R104

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

Vascular puncture?

☐ No

☒ Yes,

vessel diameter: 1 mm

☐ Aspiration performed:

☐ positive

☐ negative

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

Subject number in clinical study:

R104

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PhN-11095

Page for hospital only !  
(single blind study)

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

801113 000002

Position nr: 1

Optical spectra collected:

Experiment nr.: 17

Session number: 5

Nr. first file: 1 time: 10:49

Nr. last file: 10 time: 10:49

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: 5

Nr. first file: 11 time: 10:50

Nr. last file: 20 time: 10:54

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

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

Vascular puncture?  
(from off line analysis)

☐ No

☒ Yes,

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

Subject number in clinical study:

R104

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Disposable nr optical tissue stylet:

80 1113 000 000 2

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 problem

Subject number in clinical study:

R104

OTS VA

R1 04

Measurements to be performed:

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

Subject nr in study: \_\_\_\_\_