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Official Title: A Post-market Feasibility Study Evaluating Location Accuracy Using the superDimension™ Navigation System Version 7.2 With Fluoroscopic Navigation Technology in Subjects Undergoing Lung Lesion Biopsy

ClinicalTrials.gov ID: NCT03585959

Date of Document: 05Dec2019

Note to File

Study name:	MDT18004ILSFNV (Fluoroscopic Navigation Clinical Study)	**Investigation Site Name/ Number (if applicable):**	N/A
Subject:	Fluoroscopic Navigation Clinical Study Inclusion/Exclusion Criteria CIP Typos		

Prepared by	Katie Bayliss
Date of preparation	20 Nov 2019
Document	Fluoroscopic Navigation CIP_Final_v1.0_09Apr18

This Note to File is to document typos in the inclusion and exclusion criteria of the Clinical Investigation Plan (CIP) for the Fluoroscopic Navigation Clinical Study.

On 18Sep19 the ILS Medical Writer identified a typo in the CIP for the Fluoroscopic Navigation Clinical Study regarding the Exclusion Criteria 1. The word "not" was included in error:

> Central lesions that are ***not*** visible endobronchially or could be reached by a flexible bronchoscope or endobronchial ultrasound (EBUS) without utilization of ENB

Exclusion Criteria 1 should have stated: ee K.Bayliss 5Dec2019

> Central lesions that are ~~not~~ visible endobronchially or could be reached by a flexible bronchoscope or endobronchial ultrasound (EBUS) without utilization of ENB

[redacted]

On 29Oct19, a site Principal Investigator noticed that Inclusion Criteria 1 inaccurately states the targeted lesion size for protentional subjects:

> Subjects presents with lung lesion(s) greater than 10 mm in diameter amendable to evaluation by the ENB at the time of the evaluation

Inclusion Criteria 1 should have stated:

Subjects presents with lung lesion(s) greater than ***or equal to*** 10 mm in diameter amendable to evaluation by the ENB at the time of the evaluation

The intent of the inclusion criteria was to be consistent with the superDimension Indications for Use.

[redacted]

The CIP will not be updated as the study has been closed by the sponsor and the Site IRBs.

Name: Katie Bayliss	Role: Clinical Study Manager
Signature: Katie Bayliss	Date: 20 NOV 2019 *(dd/mmm/yyyy)*

Approved by:

Name: Melody LaBeau	Role: Director of Clinical Affairs
Signature:	Date: 20 NOV 2019 *(dd/mmm/yyyy)*