# Post-Market Study for EchoTip® Ultra High Definition Ultrasound Access Needle, the EchoTip® Ultra Endoscopic Ultrasound Needle, and the EchoTip Procore® HD Ultrasound Biopsy (MDR-2059)

**Date of Summary:** 03-March-2025

## Activity Summary Author:

Jenny Lin, MD, PhD
Clinical Scientist
Cook Research, Incorporated

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<tr><td>Investigation type</td><td>Observational, Post-market clinical investigation</td></tr>
<tr><td>Investigation design and methods used</td><td>Retrospective, single-arm, multicenter study<br><br>Devices:<ul><li>EchoTip Ultra High Definition Ultrasound Access Needle</li><li>EchoTip Ultra Endoscopic Ultrasound Needle</li><li>EchoTip Procore HD Ultrasound Biopsy Needle</li></ul>Patient Eligibility:<br>A patient was deemed eligible for inclusion in the study if the patient had a procedure using one of the above devices between January 01, 2015, and December 31, 2020.<br><br>Study Objectives:<ul><li>To confirm continued safety and performance of the device in normal intended use throughout its expected lifetime.</li><li>To confirm continued acceptability of the benefit to risk ratio.</li></ul></td></tr>
<tr><td>Sponsorship</td><td>Cook Research Incorporated (Global Sponsor)<br>1 Geddes Way<br>West Lafayette, IN 47906<br>USA<br><br>William Cook Europe, Aps (Regional Sponsor)<br>Sandet 6<br>4632 Bjaeverskov<br>Denmark</td></tr>
<tr><td>Date of first and last patient enrolled</td><td>First patient procedure date was January 2015 for both the EchoTip Ultra High Definition Ultrasound Access Needle and EchoTip Procore HD Ultrasound Biopsy Needle. The EchoTip Ultra Endoscopic Ultrasound Needle had a first patient procedure date of February 2016.<br><br>All study devices had last patient procedure dates of December 2020.</td></tr>
<tr><td>Locations</td><td>Three sites in France participated in the study.</td></tr>
<tr><td>Number of patients included</td><td><table>
<tr><th>Device</th><th># of patients</th><th># of sites</th></tr>
<tr><td>EchoTip Ultra High Definition Ultrasound Access Needle</td><td>155</td><td>3</td></tr>
<tr><td>EchoTip Ultra Endoscopic Ultrasound Needle</td><td>92</td><td>2</td></tr>
<tr><td>EchoTip Procore HD Ultrasound Biopsy Needle</td><td>93</td><td>2</td></tr>
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| **Follow-up duration** | Follow-up duration for any study needle was from the withdrawal of the needle from the accessory channel of the scope. |
| **Summary of data** | **Data availability:** All patients had technical success data available. There was no post-procedure follow-up visit requirement for the study. All available information regarding the procedural adverse events was reviewed from the medical records. Data lock for the EchoTip Ultra High Definition Ultrasound Access Needle was performed in March 2024. Data lock for the EchoTip Ultra Endoscopic Ultrasound Needle and EchoTip Procore HD Ultrasound Biopsy Needle were performed in July 2024.<br><br>***EchoTip Ultra High Definition Ultrasound Access Needle***<br><br>**Patient demographics:**<br>A total of 155 patients were enrolled. Enrollment challenges and data availability at the clinical sites precluded the study from reaching the predetermined sample size of 205 patients. Average age of the study population was 65.1 years old with a slight preponderance to male sex (54.2%, 84/155).<br><br>**Technical success:**<br>Technical success was defined as the ability to achieve access (to facilitate placement of a guide-wire or injection) or obtain a sample without any technical failure of the needle which necessitated the use of a new needle. Technical success was observed among 99.3% (151/152) patients. Difficult or altered anatomy was cited as the reason for technical failure in 1 patient, with additional details specifying that the thinness of the bile ducts made it impossible to effectively implant the guide wire. The technical success rate observed in the current study meets the performance goal of 90% set for the study. There was no evidence of systematic off-label use.<br><br>**Adverse Events:**<br>There were no pre-determined safety measures per the study plan. Two adverse events among 2 patients were reported (1.3%, 2/155). One event was reported as unsuccessful aspiration and the other event was blood clot in the guidewire. Neither were deemed by clinical site Principal Investigator (PI)s as device- or procedure- related or serious or unexpected.<br><br>***EchoTip Ultra Endoscopic Ultrasound Needle***<br><br>**Patient demographics:**<br>A total of 92 patients were enrolled. Average age of the study population was 64.8 years old with a slight preponderance to male sex (55.4%, 51/92).<br><br>**Technical success:**<br>Technical success was defined as the ability to obtain a sample without any technical failure of the needle which necessitated the use of a new needle. Technical success was observed among 98.8% (81/82) of on-label patients. Technical success was calculated with exclusion of the 7 off-label patients with coagulopathy contraindication and 3 off-label patients with rectal lesion sampling. For the 1 patient in whom technical success was not achieved, the reason was reported as difficult or altered anatomy due to bad positioning of the patient and was not deemed a device deficiency. One patient had reported technical success, but noted a device issue of "difficulty aspirating liquid". The technical success rate observed in the current study meets the performance goal of 92% set for the study. There was no evidence of systematic off-label use. |

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| | **Adverse Events:**<br>Although there were no pre-determined safety measures per the study plan, all sites were instructed to report any adverse events a patient had during the procedure if they occurred. A single adverse event (respiratory depression treated medically with intubation) was reported (1.1%, 1/92). The event was deemed by the clinical site PI as not serious or unexpected and was not procedure- or device-related. There were no procedure- or device-related complaints.<br><br>***EchoTip Procore HD Ultrasound Biopsy Needle***<br><br>**Patient demographics:**<br>A total of 93 patients were enrolled. Average age of the study population was 69.5 years old with a slight preponderance to male sex (53.8%, 50/93).<br><br>**Technical success:**<br>Technical success was defined as the ability to obtain a sample without any technical failure of the needle which necessitated the use of a new needle. Technical success was observed among 100.0% (85/85) on-label patients. Two patients where the needle was used for puncture (rather than sampling) and the 6 patients with a coagulopathy contraindication were excluded for this analysis. The 1 patient with rectal lesion sampling also had a coagulopathy. Among all of these off-label patients, needles were reported as technically successful for their purpose. The technical success rate observed in the current study meets the performance goal of 99% set for the study. There was no evidence of systematic off-label use.<br><br>**Adverse Events:**<br>Although there were no pre-determined safety measures per the study plan, all sites were instructed to report any adverse events a patient had during the procedure if they occurred. No adverse events were reported among 93 patients. There were no procedure- or device-related complaints. |