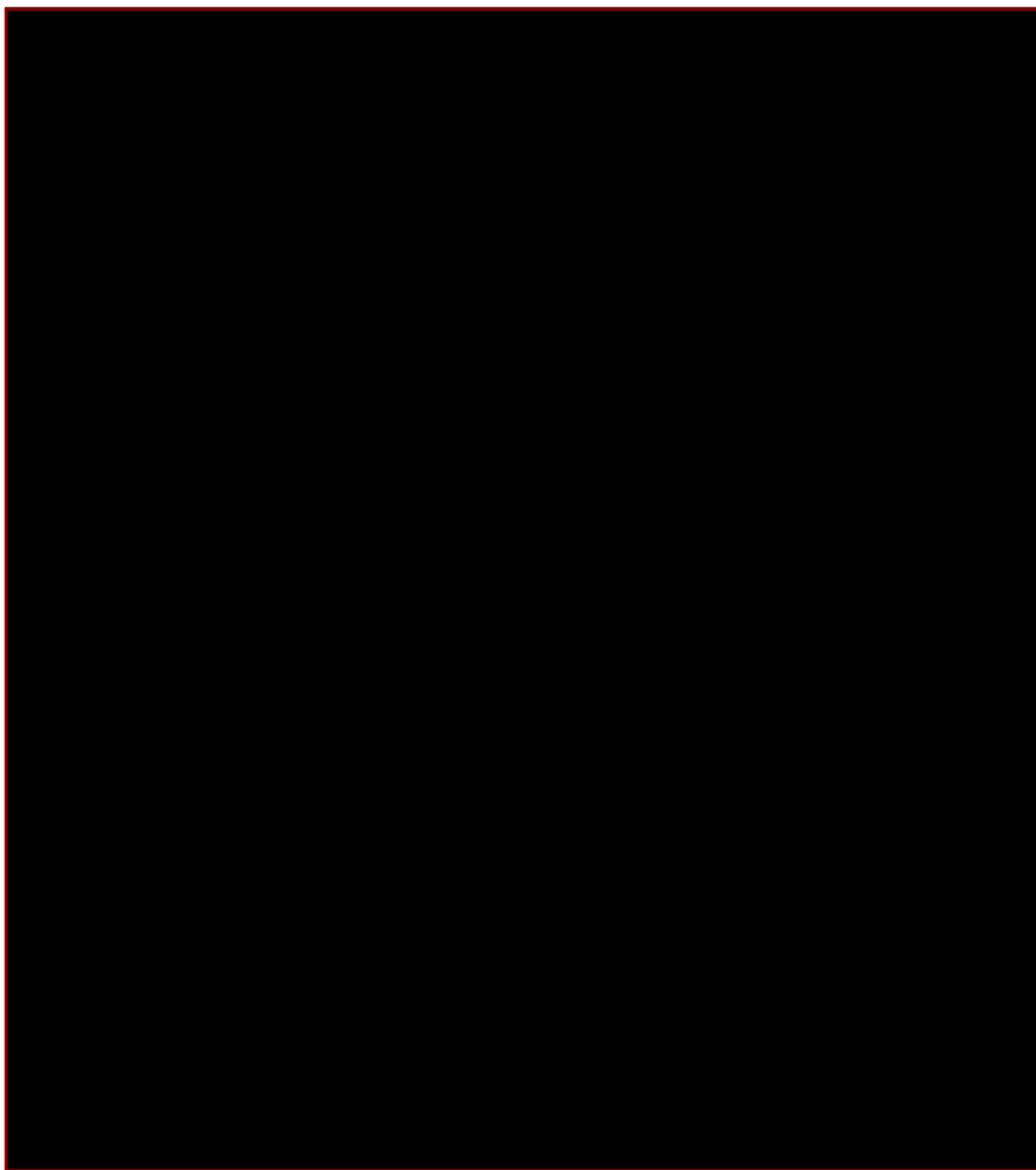
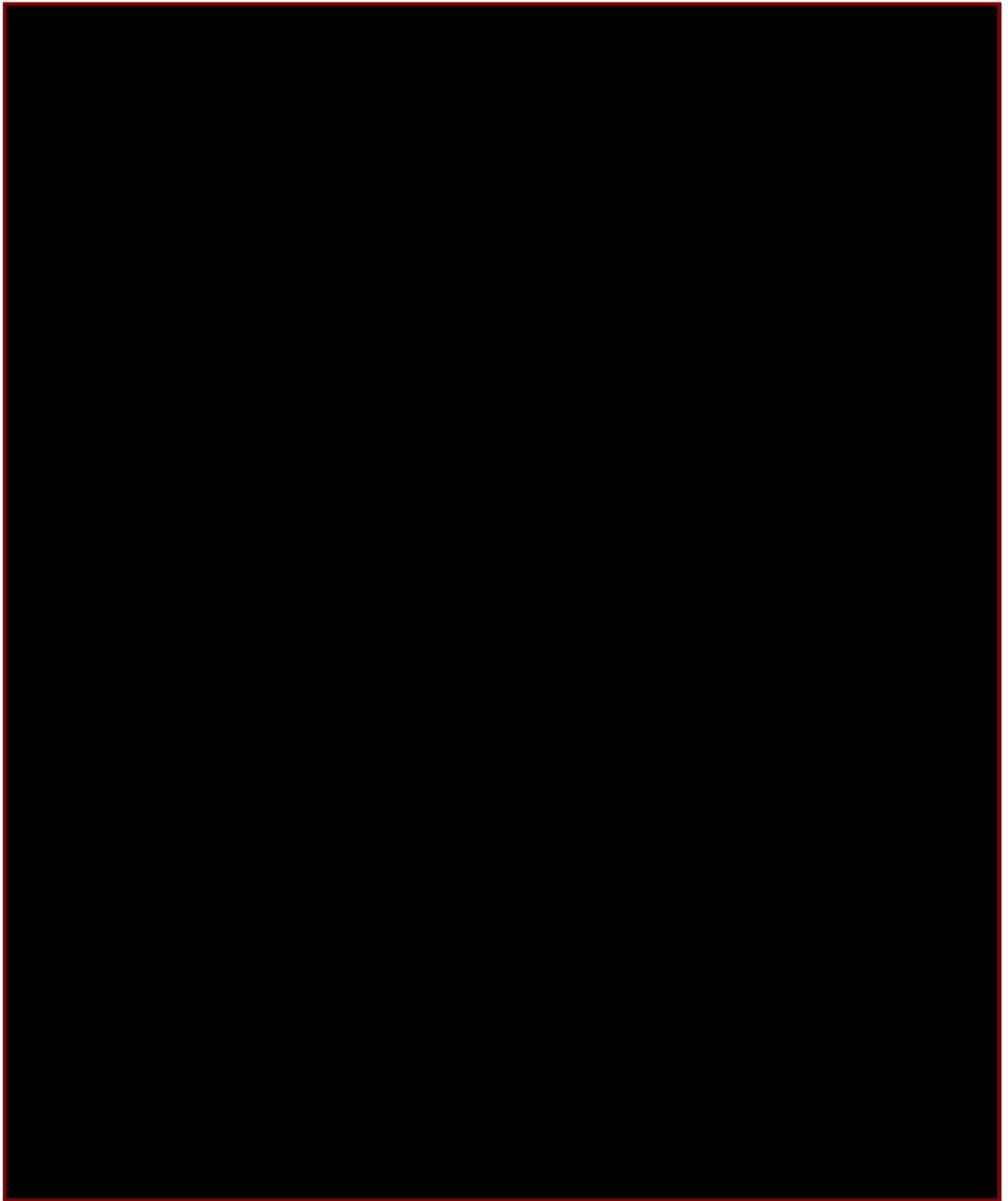


## **X. POST-TRIAL DEVICE CHANGES**

**X. A. PUSH ROD SHAPE AND BAND SPACING  
CHANGES**





**SECTION BREAK**

#### 4.2.3.3 Post Trial Modifications

[REDACTED] FDA responded with questions and these changes were finally approved on [REDACTED]

The supplement proposed numerous changes to the protocol and to the device. However, changes to the catheter itself included a new 5F outer shaft to be compatible with a 5F hysteroscope working channel, and a modified internal shaft construction to function with the new handle and smaller shaft. The sheath at the distal tip was modified to extend the full length of the catheter, over the push rod, and attach to the release mechanism in the handle. The push rod was also extended back into the handle. [REDACTED]

[REDACTED]

During clinical use of this catheter version in the EASE trial, 8 failures similar to those seen in the earlier version were identified. Following the EASE trial two interrelated modifications have been made to the Delivery Catheter; these changes address push rod failures that have occurred with the current design. These modifications were generated to improve push rod effectiveness and Matrix delivery reliability with the modified device. These changes include:

[REDACTED]

Pages 1107-1137 have been removed.