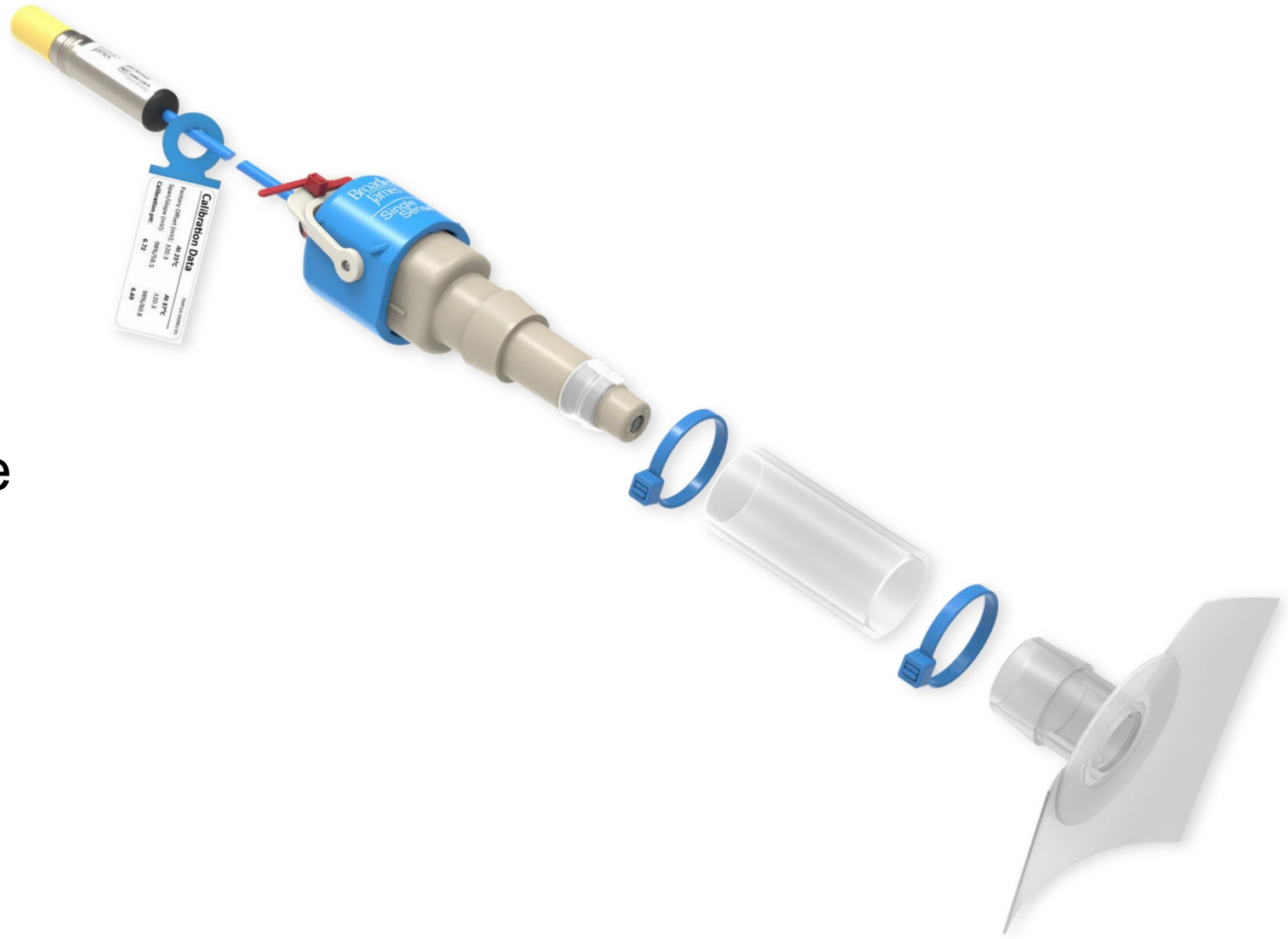
Broadley James

Installation Manual

SingleSense® Single-Use pH Sensor

Model SU800



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Purpose

This manual provides instructions on how to install the SU800 SingleSense® Single-Use pH Sensor for use with a bioprocess container (BPC).

Scope

This manual is for customers who purchase and use the SU800 SingleSense® Single-Use pH Sensor.

Precautions

This product is intended for professional use only. Follow your standard operating procedures when using this product. Do not use the product if it is broken, defective, or visually damaged.

Compliance

Broadley-James Corporation confirms Model SU800 SingleSense® Single-Use pH Sensor meets the following regulatory and compliance standards:

CE Compliant	Yes
RoHS Compliant	Yes
REACH Compliant	Yes
CFR 21-11 Compliant	Not applicable
BSE/TSE/ADI Free	Yes
USP Class VI Compliant	Yes, all wetted parts
FDA Material Compliant	Yes, all wetted parts

Wetted Materials

PEEK: UPS Class VI, ADI-Free, Extraction Tested 21CFR, 177 | Dimethyl Silicone Rubber: Pt Cure, USP Class VI, Extraction Tested 21 CFR, 177 | EPDM: USP Class VI, FDA Compliant, ADI-Free | Lead-Free Glass | Alumina Silicate

Full scale extractable and leachable test based on BPOG extractable protocol and USP 665 pending.

Product Description

The SU800 SingleSense® Single-Use pH Sensor is gamma sterilizable and designed for use with a BPC.

Definition of Symbols

REF	Catalogue number
SN	Serial number
CE	CE marking
	Use by date
	Temperature limit
QTY	Quantity

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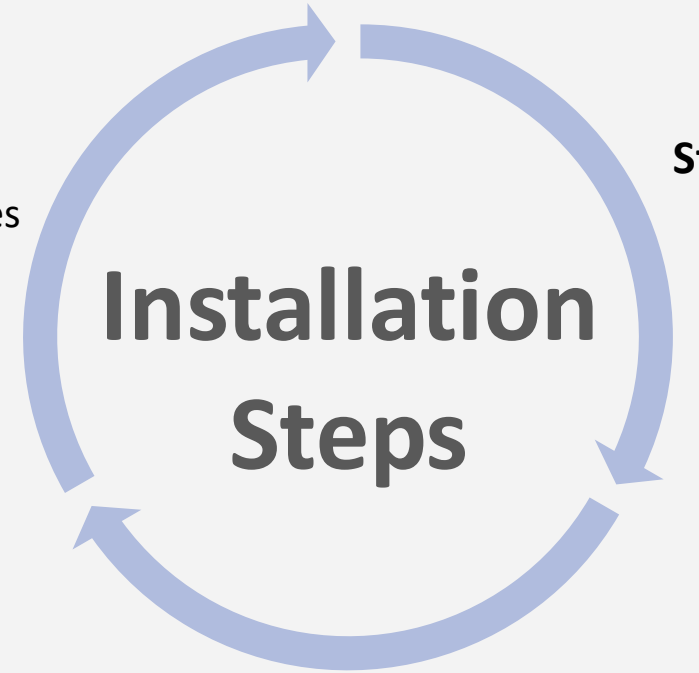

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Step 1: Preparation

- Recommended Equipment and Supplies
- Essential Terms and Definitions
- Sensor Description
- Unpacking the Sensor

1.1 Recommended Equipment and Supplies

The following materials are recommended to complete the installation.

Item	Quantity	Description
Eldon James 1-inch barbed port or equivalent	1	The sensor is designed to be used with an Eldon James barbed port.
Isopropyl alcohol	As required	Isopropyl alcohol may be used as a lubricant. Follow your standard operating procedures on the use of isopropyl alcohol.
Silicone tube (See **Appendix B** for dimensional drawing)	1	The silicone tube is placed over the sensor and barbed port. The tube needs to be precut to a length between 2.4 in and 2.5 in.
Zip ties	As required	The zip ties will be used to secure the silicone tube to the barbed feature of the sensor and barbed port. Follow your standard operating procedure on the use of zip ties.
Zip-tie tool or fastener	1	The tool is used to secure the zip ties.

1.2 Essential Terms and Definitions

This table outlines terms and definitions important for the installation process. See the next slide for their location on the sensor.

Term	Definition
Barbed feature	Section of the sensor body that is used to create a seal with the silicone tube and barbed port
Buffer storage chamber	Houses and protects the glass pH sensor within the sensor body
Calibration tag	Tag on the sensor's cable that displays data specific to each sensor (do not remove)
Yellow protective cap	Protects the VP8 connector during shipment
Lever arm	Retracts and inserts the glass pH sensor
Protective end cap	Protects the end of the sensor prior to BPC installation
Red safety zip tie	Designed to keep the sensor in the retracted position for shipment
Top housing	The top housing moves with the glass pH sensor. It moves up when the glass pH sensor is retracted and down when the glass pH sensor is extended. **Important:** The logo must be facing upward on the top housing for proper installation.

1.3 Sensor Description

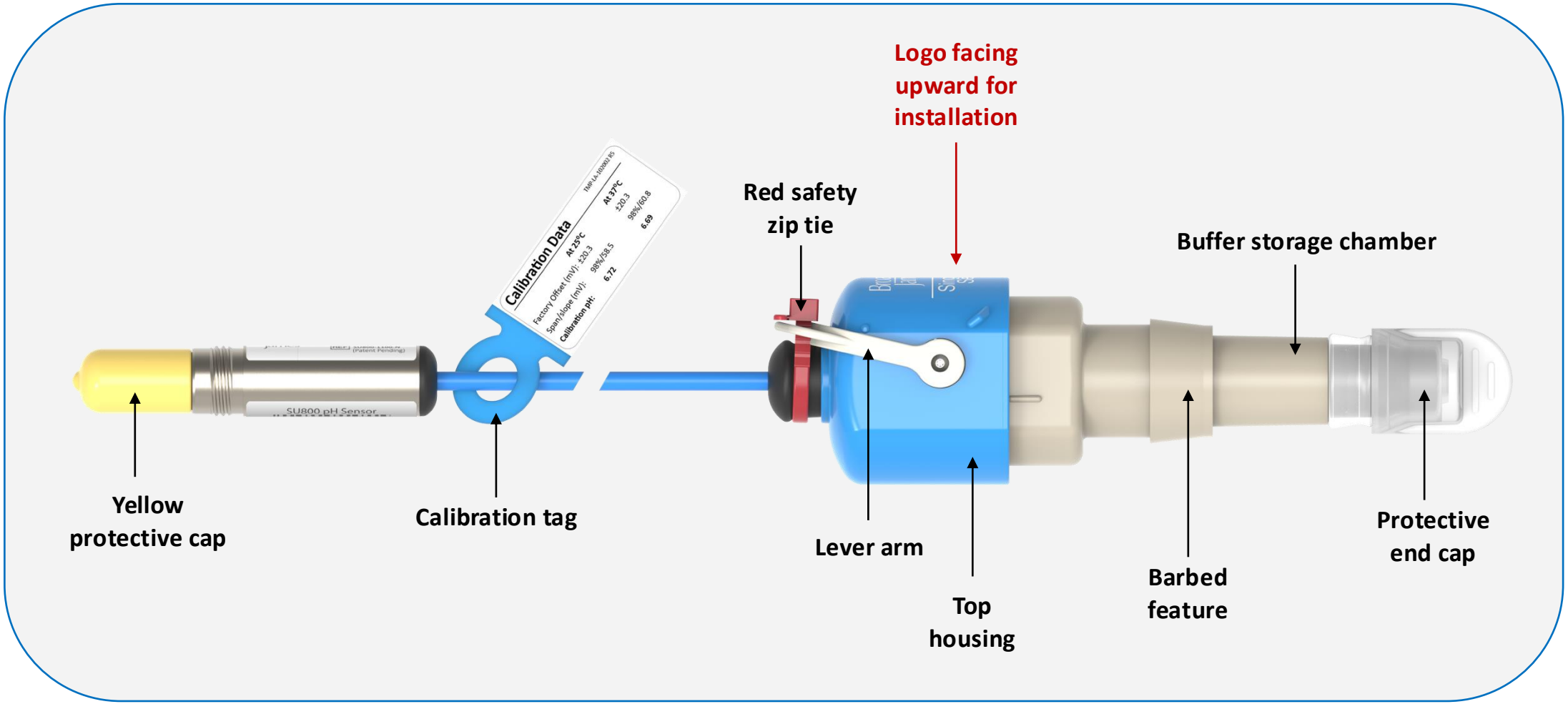


Figure 1. Sensor description

1.4 Sensor Packaging Configuration

- The sensor is double bagged.
- The outer bag protects the inner bag.
- The inner bag is sealed in a Class 7 clean air hood.
- All labeling on the inner bag is legible through the outer bag.

Figure 2. Sensor packaging configuration

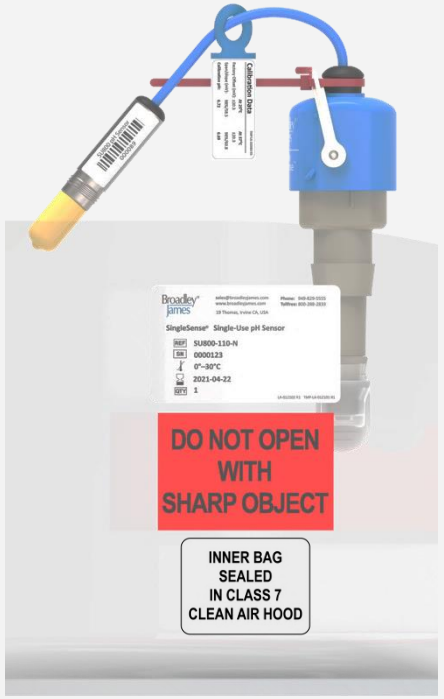
1.5 Unpacking the Sensor

- Remove the outer bag from the sensor package and transfer the inner bag to a clean room.
- When inside a clean room, carefully open the inner bag and remove the sensor.

⚠ Do not remove the calibration tag.

Note: Do not damage the sensor's cable during removal. Only open the inner bag in a clean room.

Remove from outer bag



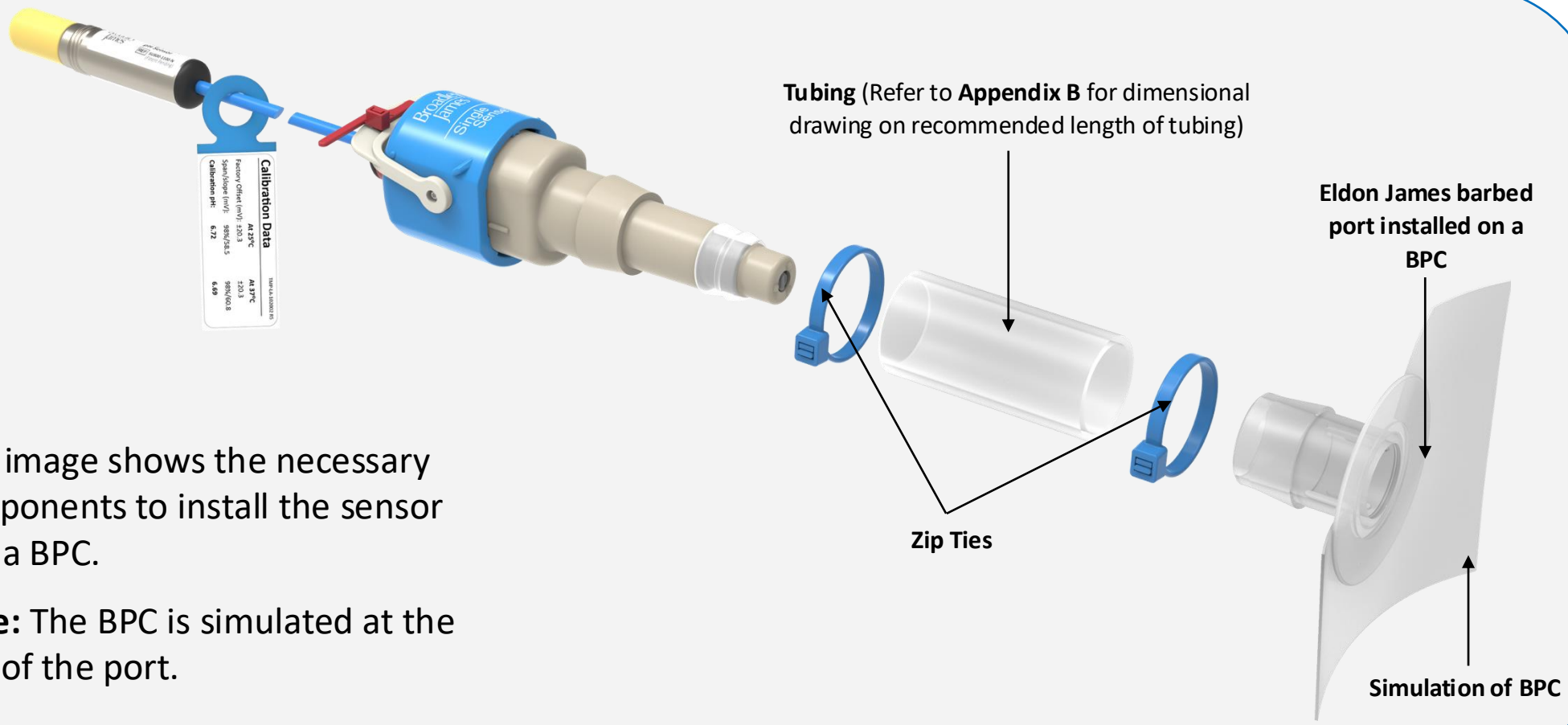
Remove from inner bag only when in a clean room

Figure 3. Unpacking the sensor

Step 2: Installation

- Installation Overview
- Install Tubing
- Remove Protective Cap
- Secure Zip Ties

2.1 Installation Overview



This image shows the necessary components to install the sensor into a BPC.

Note: The BPC is simulated at the end of the port.

Figure 4. Sensor installation components with simulated BPC

2.2 Install the silicone tube on the Eldon James barbed port.

- For ease of installation, lubricate the internal surface of the silicone tube with isopropyl alcohol.
- Follow your standard operating procedure on the use of isopropyl alcohol.

Note: Part of the BPC is simulated in the image.

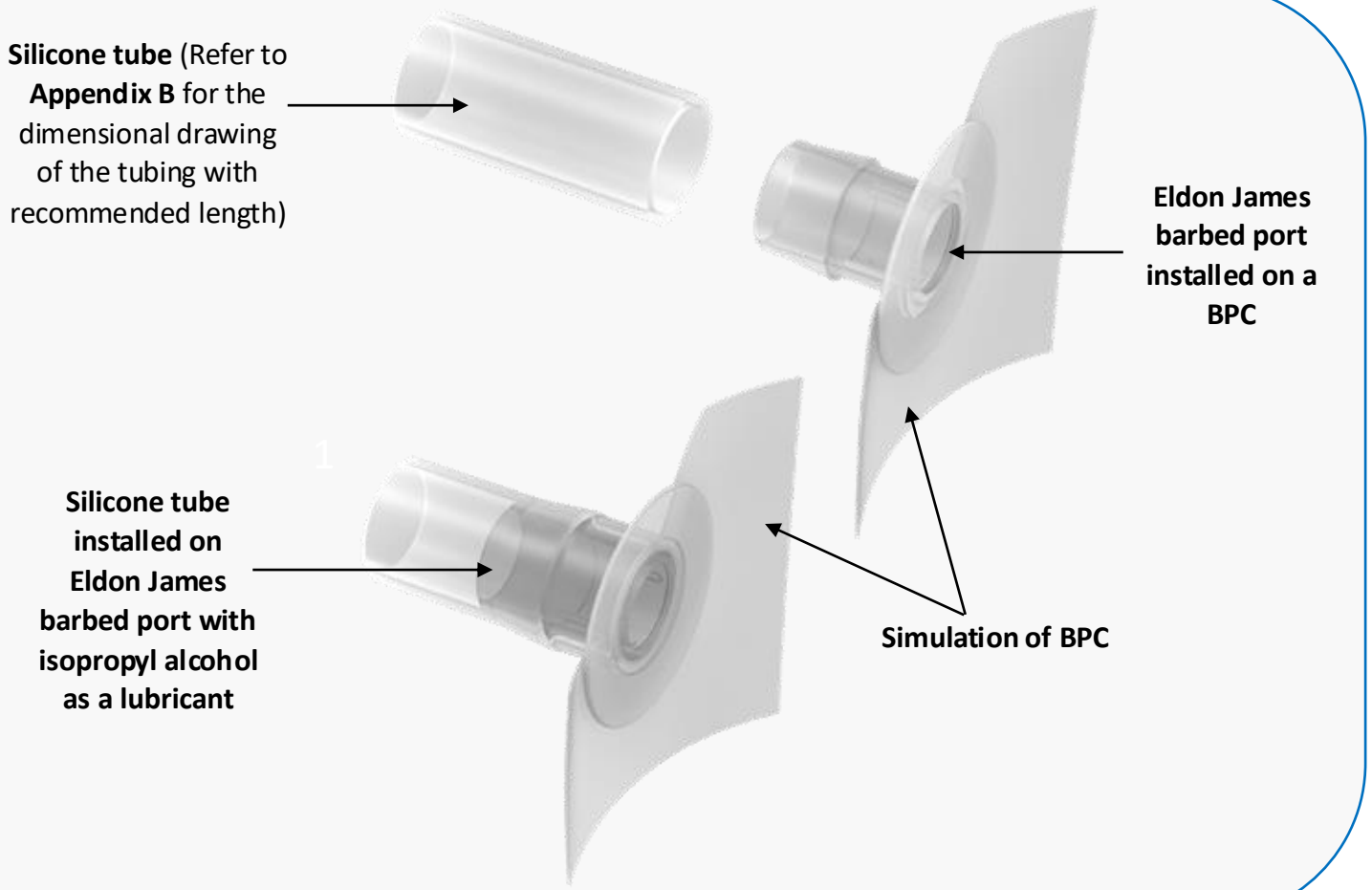
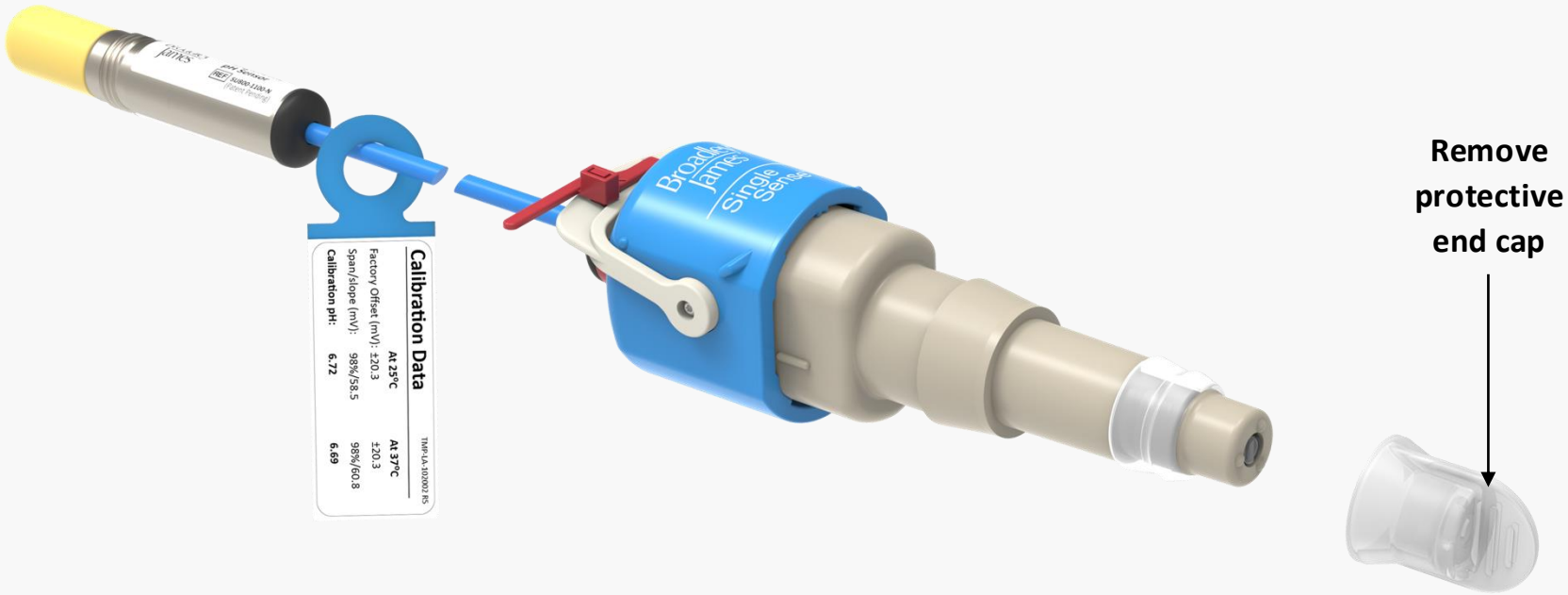


Figure 5. Silicone tube installation

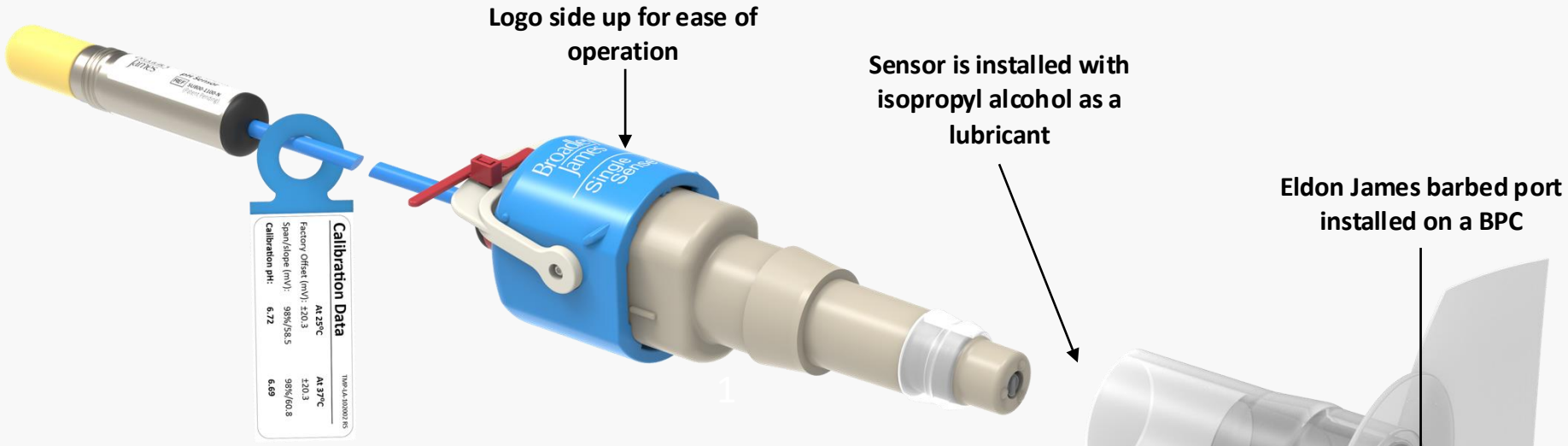
2.3 Remove the protective end cap.



⚠ **Do not remove** the yellow protective connector cap or red safety zip tie. The calibration tag should remain attached throughout the installation process.

Figure 6. Protective end cap removal

2.4 Install the sensor into the silicone tube and barbed port.



- For ease of installation, lubricate the internal surface of the silicone tube with isopropyl alcohol.
- Follow your standard operating procedure on the use of isopropyl alcohol.

Note: A rolled or missing gasket does not impact product use or integrity.

Figure 7. Sensor installed with silicone tube and barbed port

2.5 Secure the silicone tube with zip ties.

- We recommend using a zip tie at each end as shown.
- To ensure best fit, use of a zip-tie tool or fastener is recommended.
- Follow your standard operating procedure on the use of zip ties.

Note: Part of the BPC is simulated in the image.

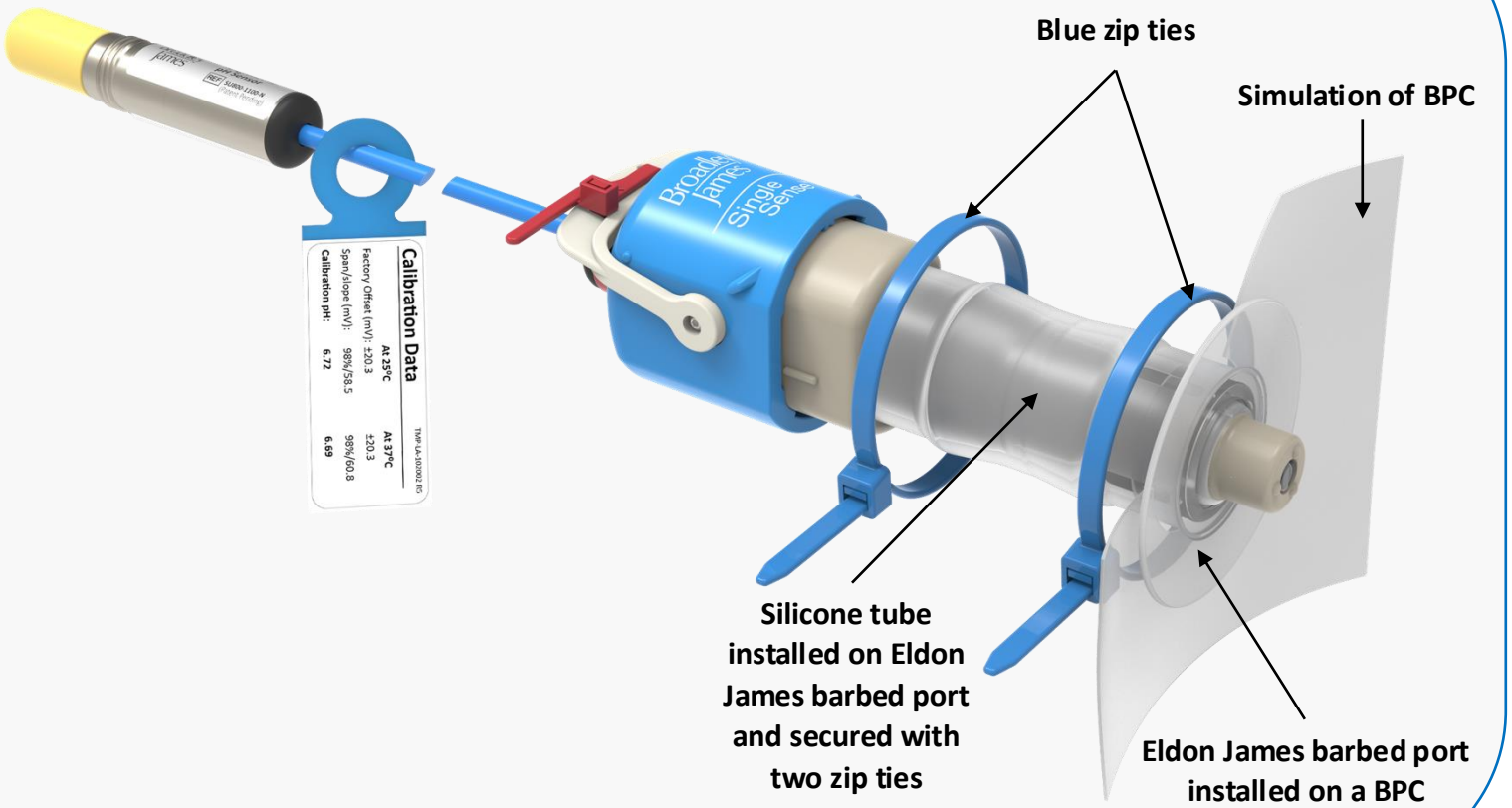


Figure 8. Zip tie placement

2.6 Clip the ends of the blue zip ties after securing a tight fit.

This completes the installation process. We recommend bubble wrapping the sensor prior to final packaging with the BPC.

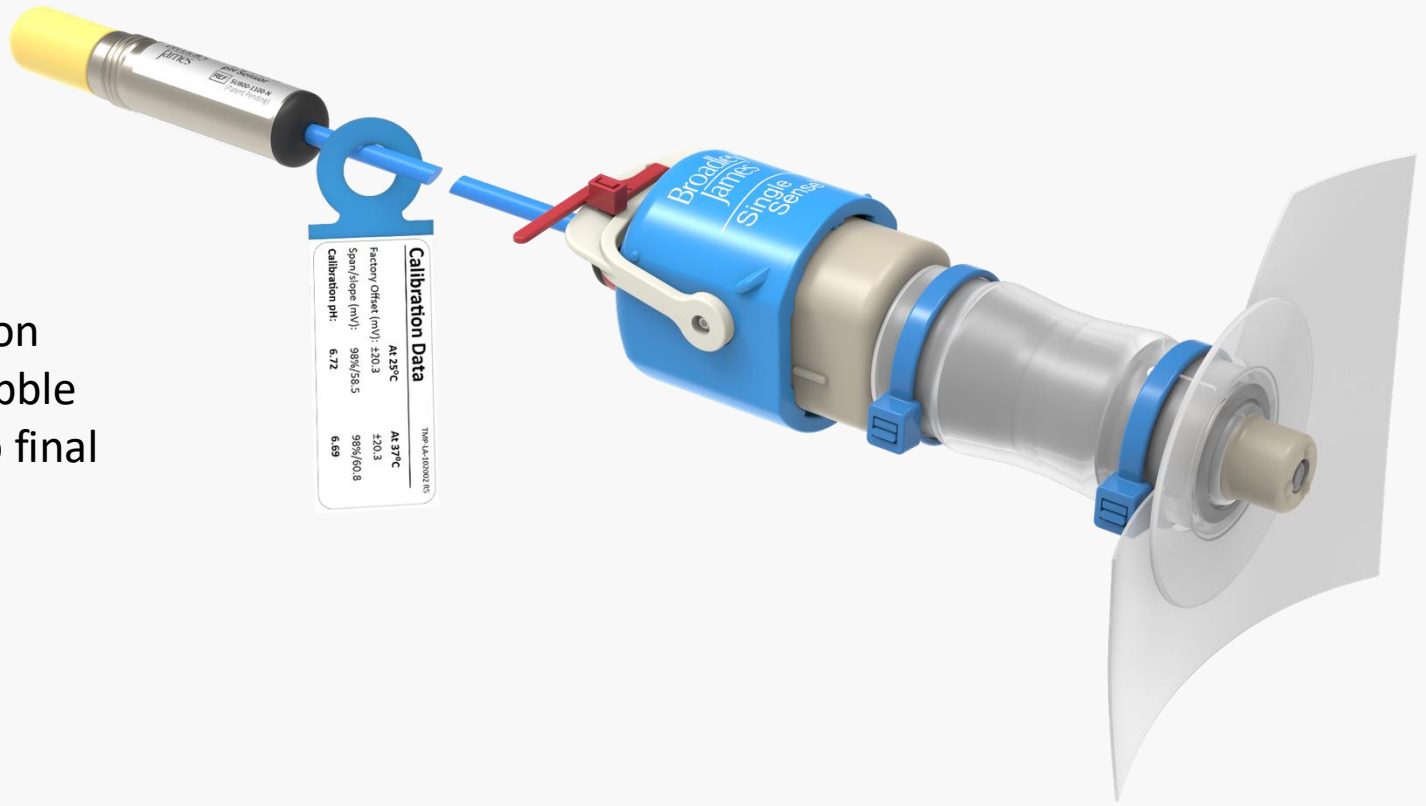
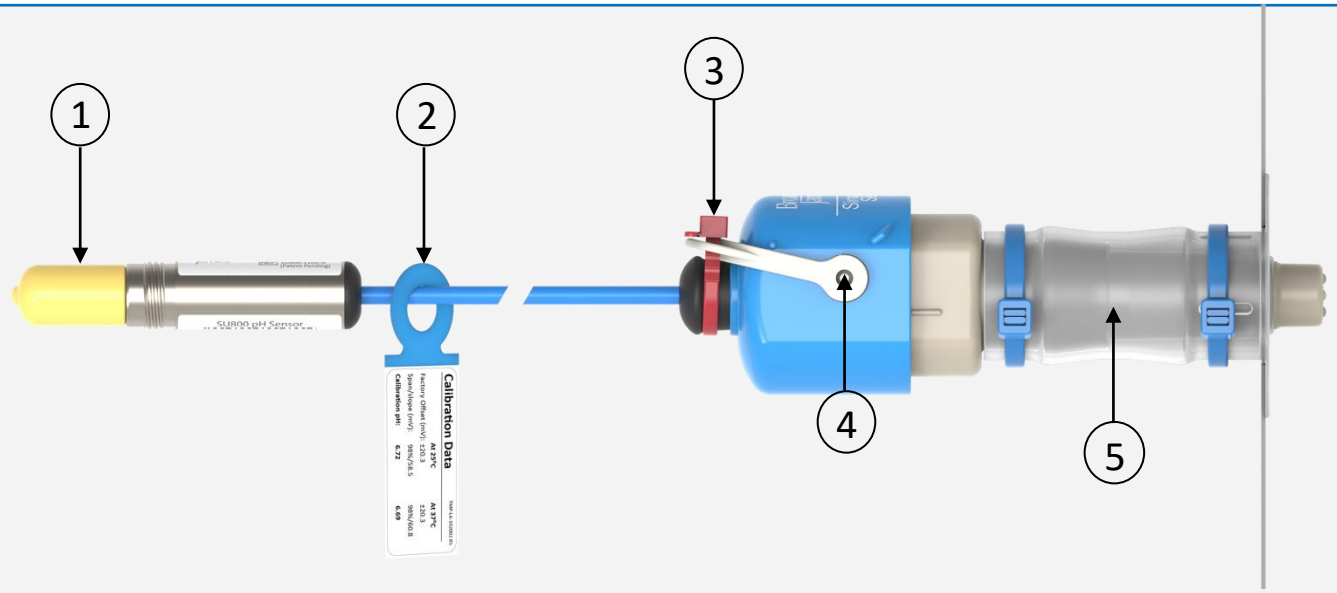


Figure 9. Sensor final installation

Step 3: Post-Installation Inspection

- Inspection Checklist
- Packaging Recommendations
- Final Bubble Wrap

3.1 Post-Installation Inspection Checklist



- ☐ **1.** Is the yellow protective cap on?
- ☐ **2.** Is the tag on the sensor cable?
- ☐ **3.** Is the red safety zip tie on the sensor?
- ☐ **4.** Is the lever arm tied back?
- ☐ **5.** Do the barbed features touch?

Important: We recommend bubble wrapping the sensor to prevent damage during shipment.

Figure 10. Inspection checklist

Appendices

- Appendix A – Dimensional Drawing of Installed Sensor
- Appendix B – Dimensional Drawing of 1-inch Silicone Tube
- Appendix C – Dimensional Drawing of Eldon James Barbed Port
- Appendix D – Dimensional Drawing of Tubing Fit

Appendix A – Dimensional Drawing of Installed Sensor

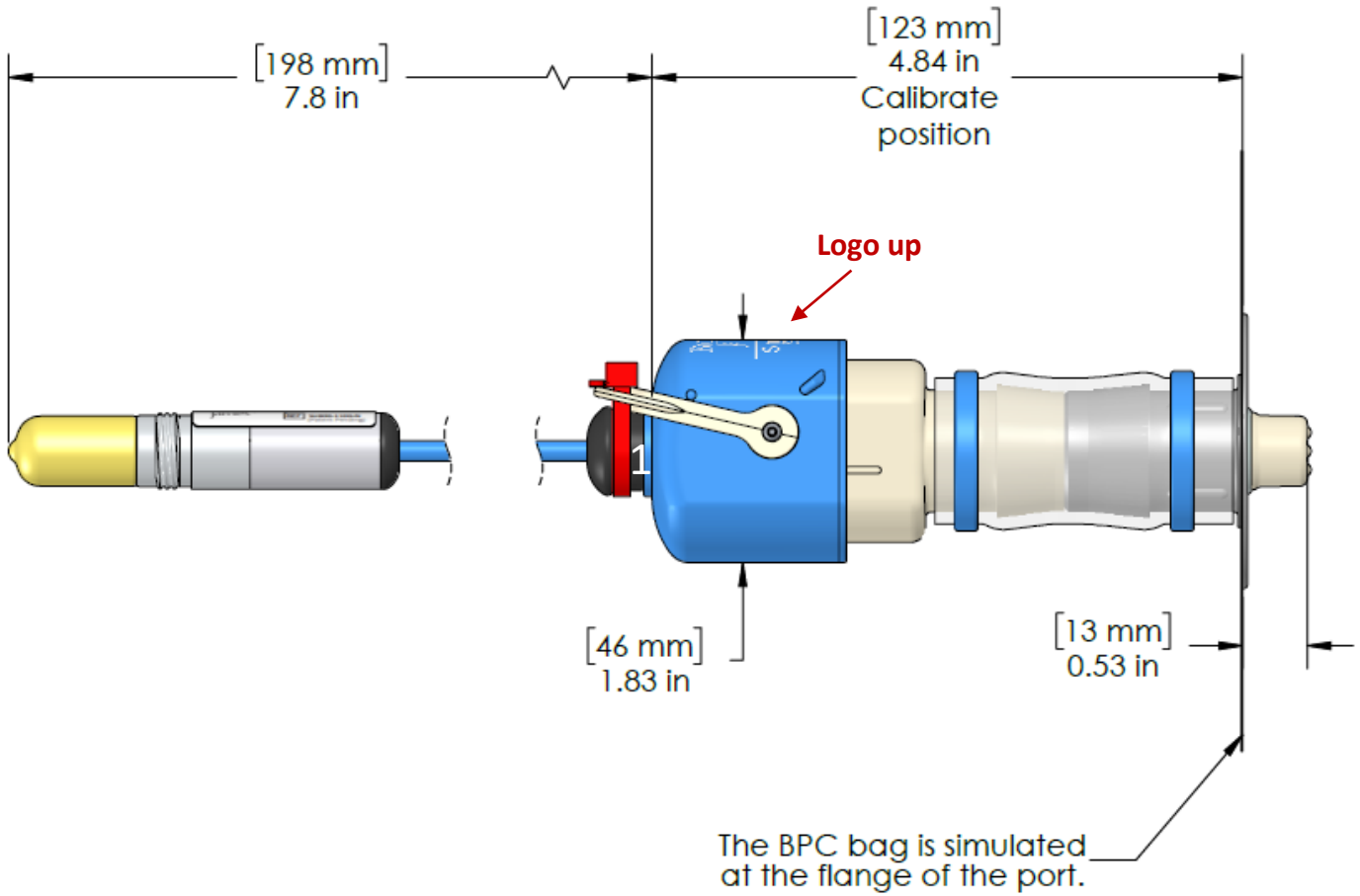
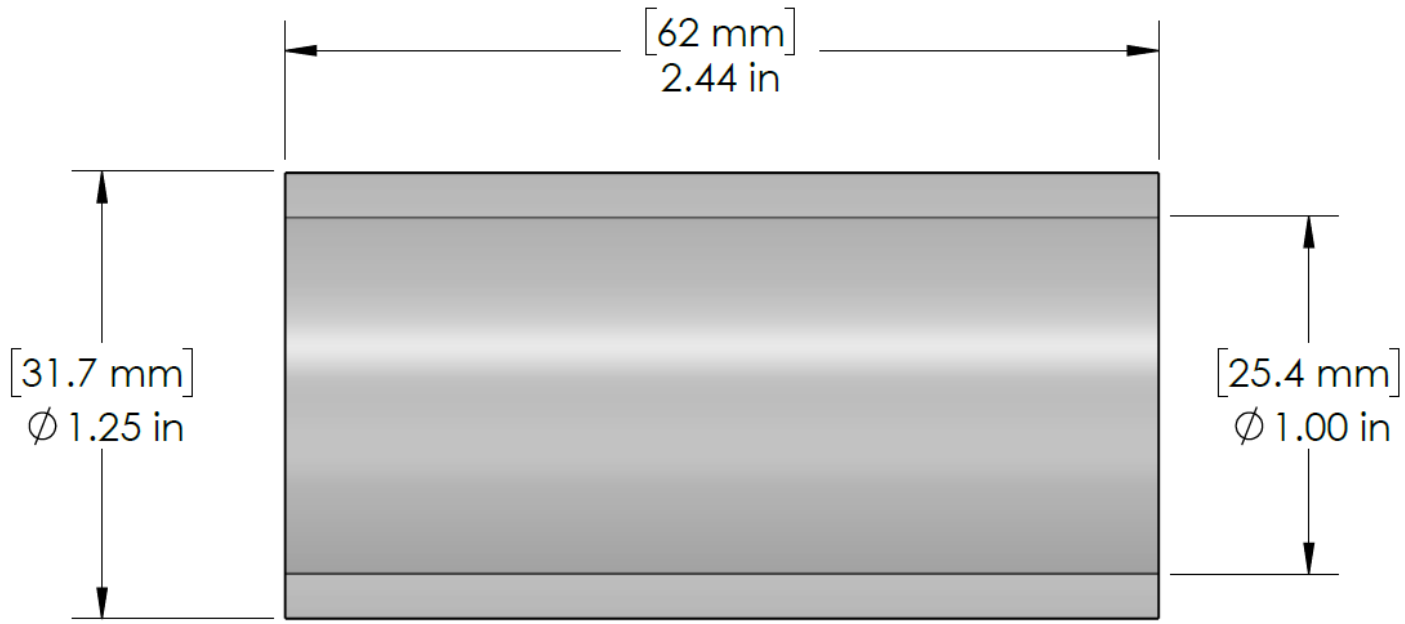


Figure 11. Dimensional drawing of sensor

Appendix B – Dimensional Drawing of 1-inch Silicone Tube



These are nominal dimensions that will guarantee that the barbed feature of the sensor will touch the barbed feature of the Eldon James port.

Figure 12. Dimensional drawing of 1-inch silicone tube

Appendix C – Dimensional Drawing of Eldon James Barbed Port [1]

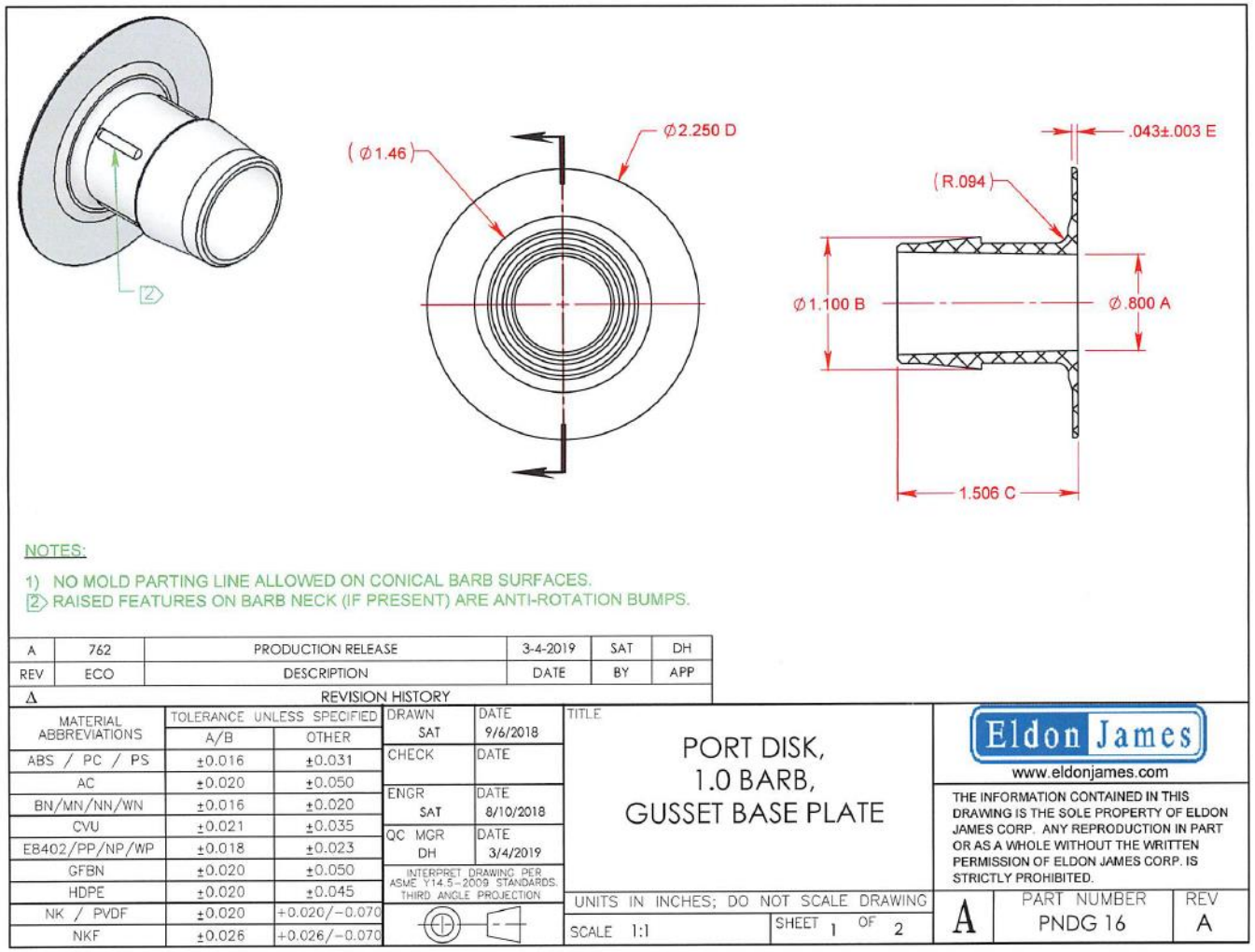


Figure 13. Dimensional drawing of barbed port

[1] This dimensional drawing was provided by Eldon James Corporation. See Eldon James Corporation for the latest revision of this drawing.

Appendix D – Dimensional Drawing of Tubing Fit

This dimensional drawing shows the proper tubing fit. The barbed features are designed to meet and touch in order to create a strong seal.

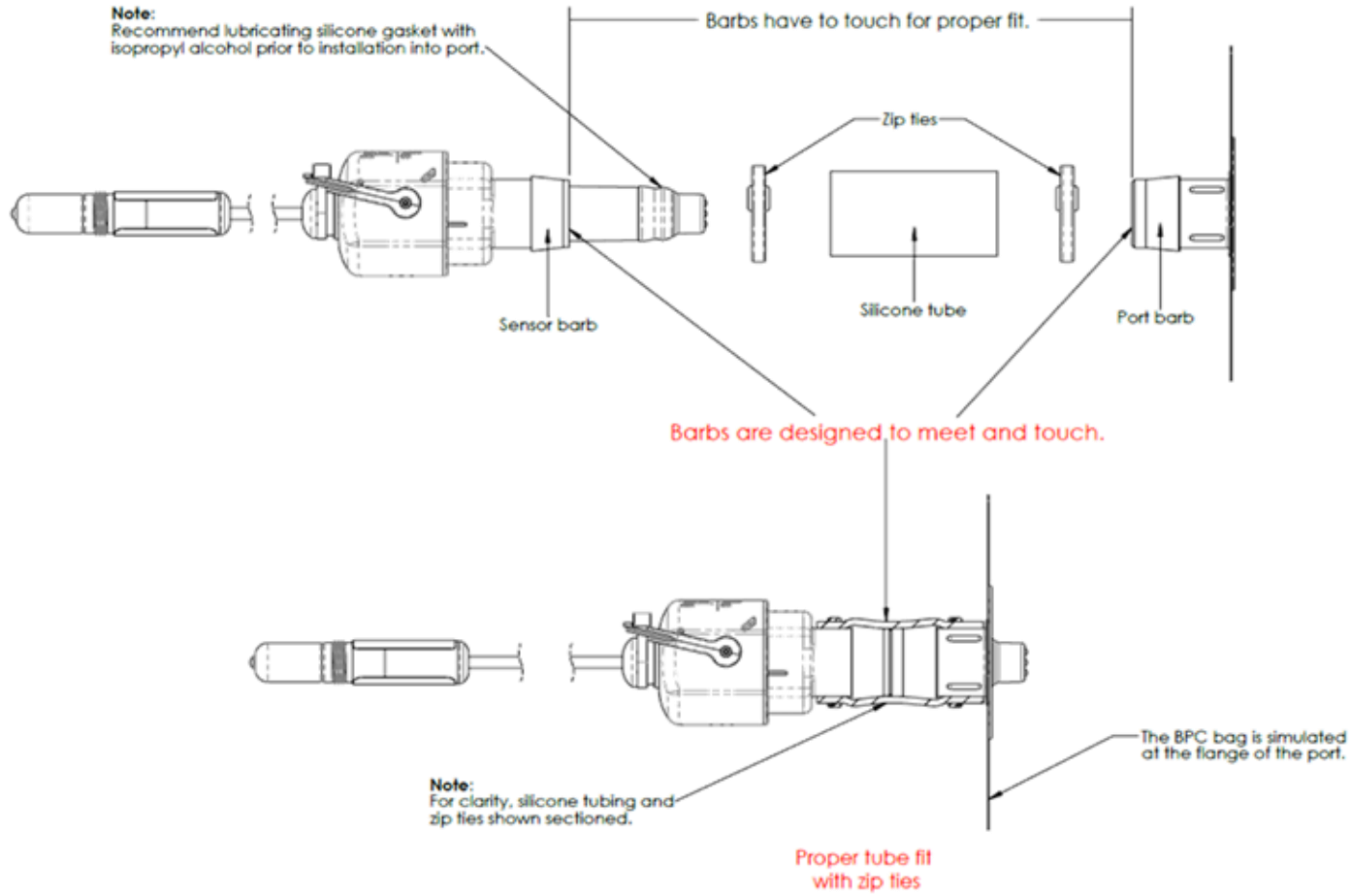


Figure 14. Dimensional drawing of tubing fit

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