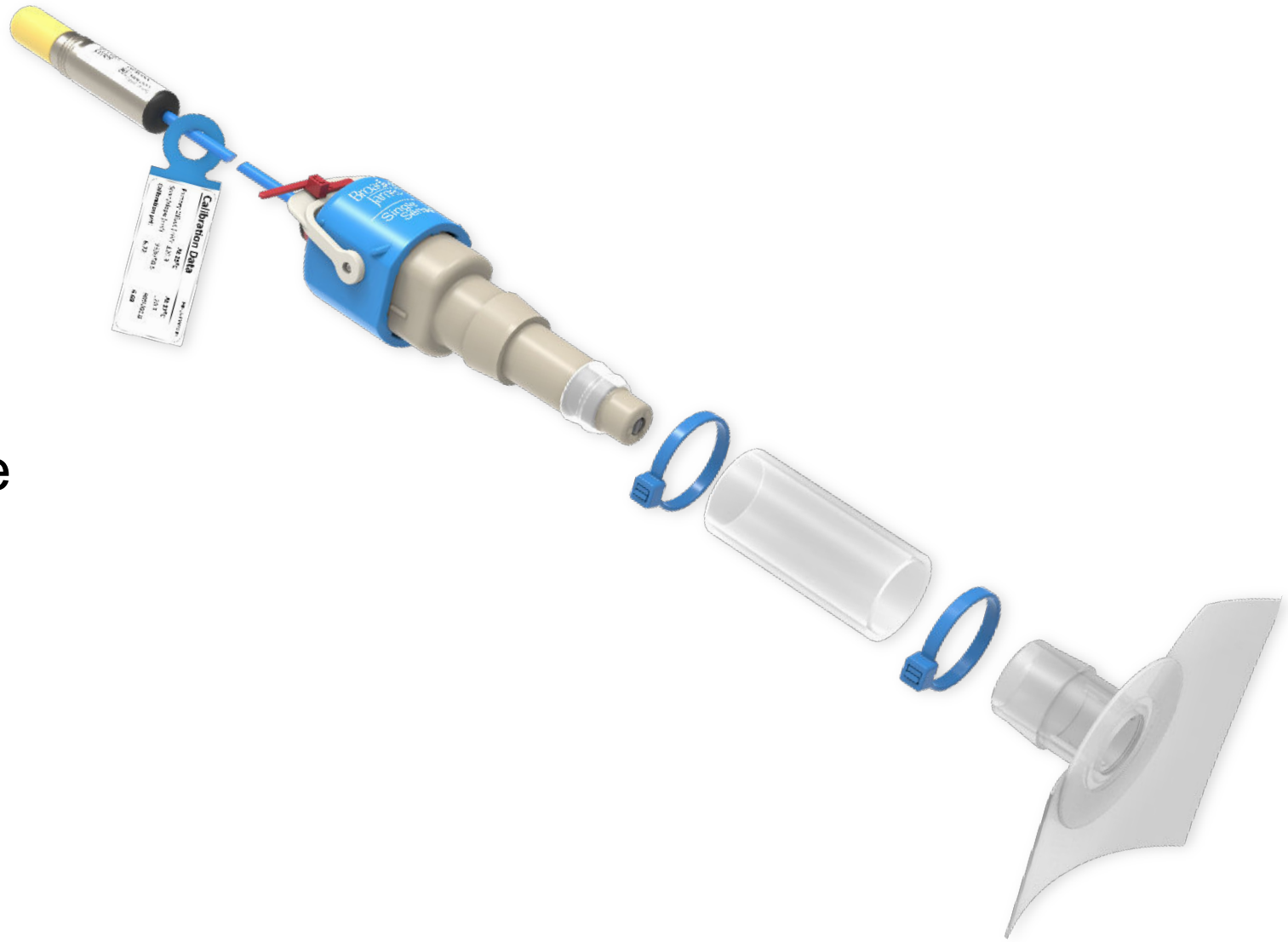
Broadley James®
Manufacturers of Sensors for Science and Industry

Installation Manual

SingleSense® Single-Use pH Sensor

Model SU800



PATENTED
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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.

Disclaimers

Read all instructions prior to installing or operating this product. Save this manual for future reference.
If the instructions in this manual are unclear, contact Broadley-James. If this instruction manual is not for the product ordered, call (949) 829-5555.
Follow all warnings, cautions, and instructions marked on and supplied with the product.
To ensure proper performance, use qualified personnel to install, operate, update, calibrate, and maintain the product.
This product is designed for single-use.

Third-Party Content

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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, 177.2600 | Dimethyl Silicone Rubber: Pt Cure, USP Class VI, Extraction Tested 21 CFR, 177.2600 | 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

Table of Contents

Installation Steps

Step 1: Preparation

- Recommended Parts and Supplies
- Essential Terms
- Sensor Description
- Unpacking the Sensor

Step 2: Installation

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

Step 3: Post-installation Inspection

- Inspection Checklist
- Packaging Recommendations
- Final Bubble Wrap

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

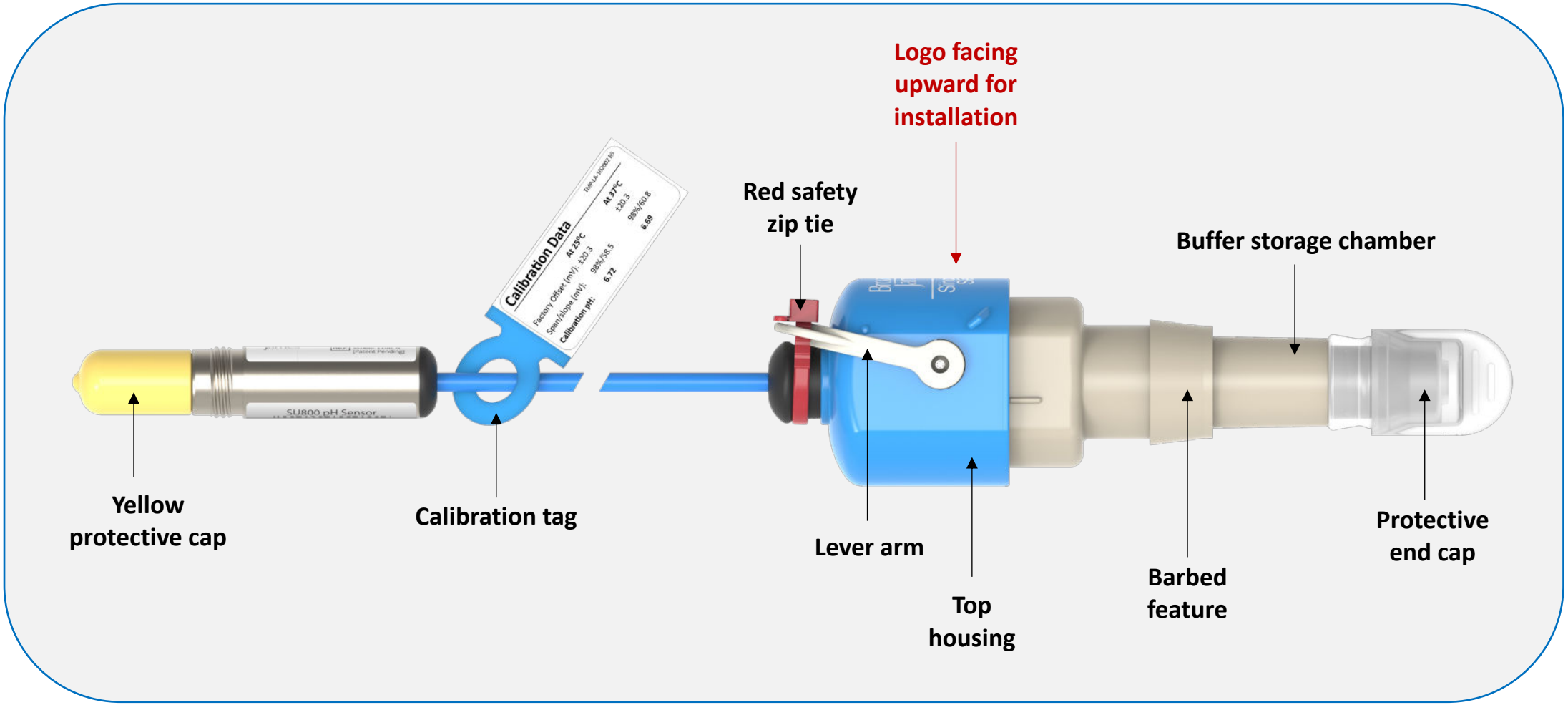


Figure 1. Sensor description

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

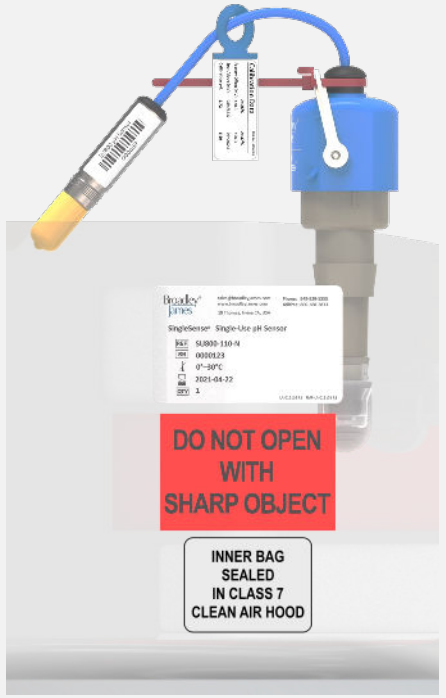
1.5 Unpacking the Sensor

- 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



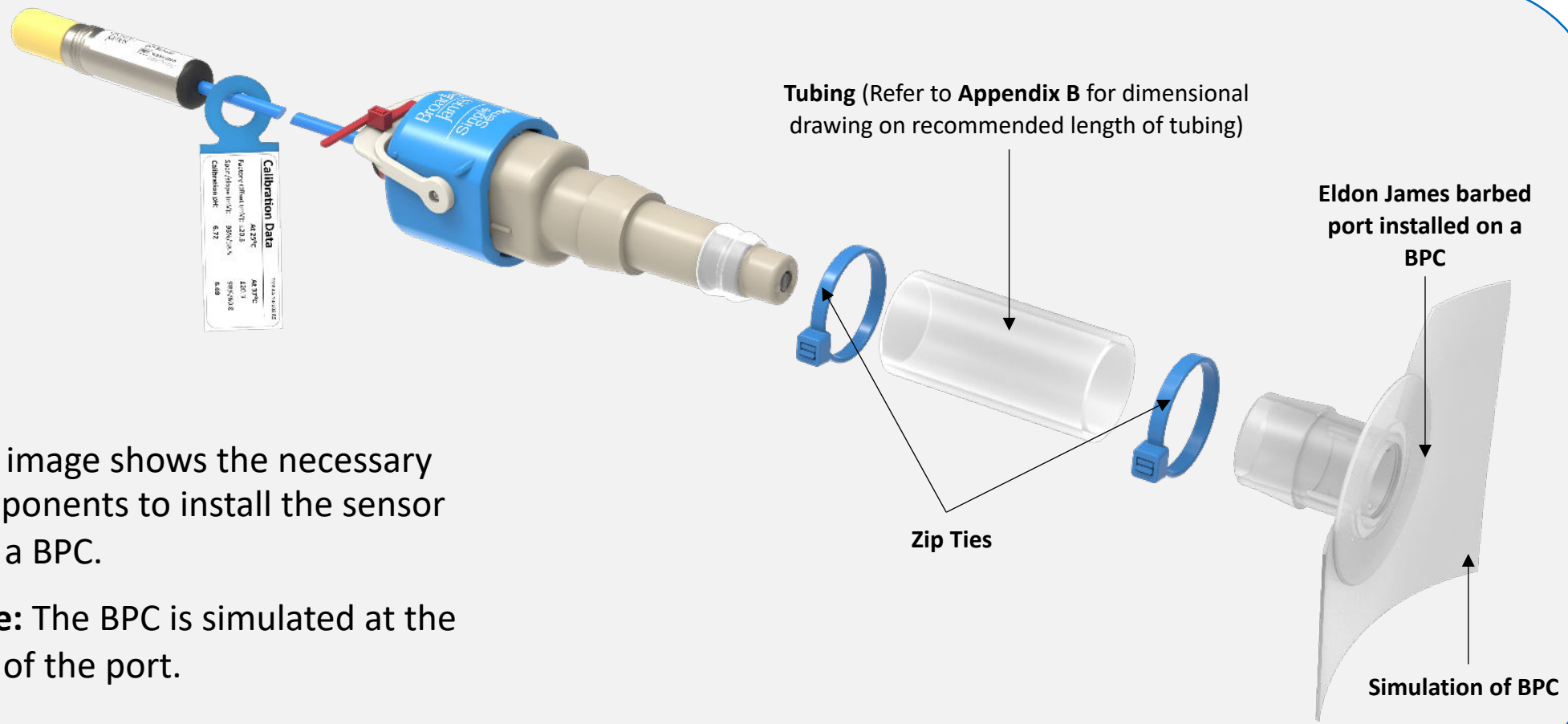
Remove from inner bag only when in a clean room

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.

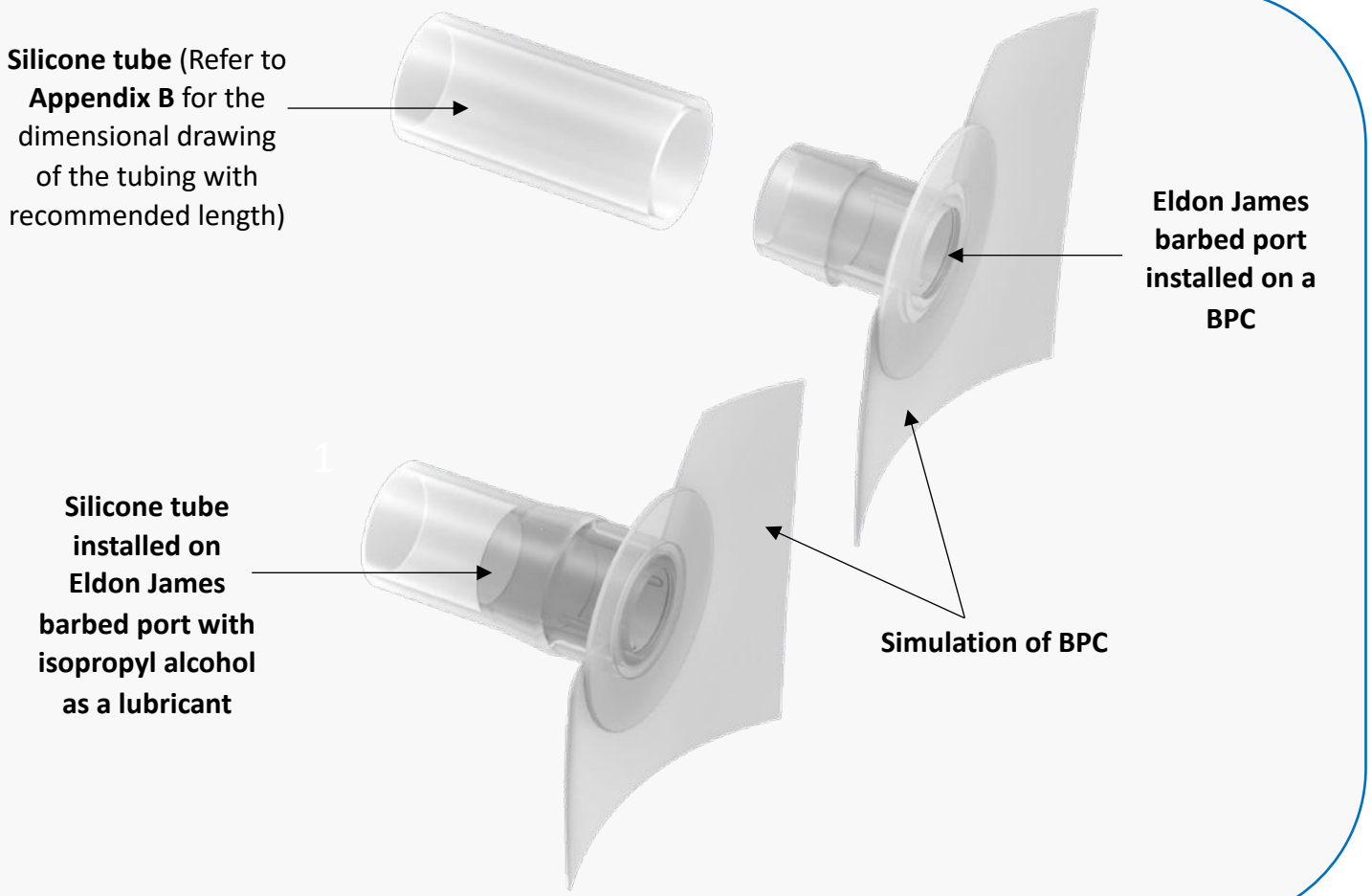
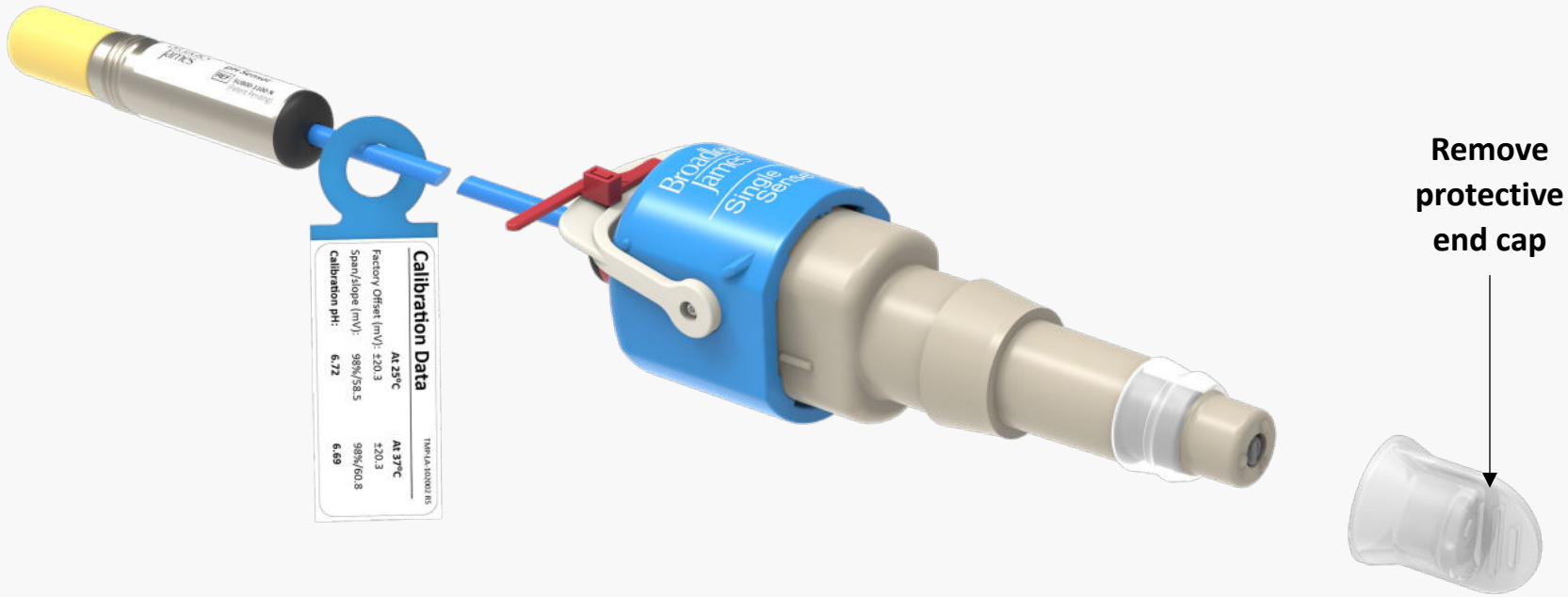


Figure 5. Silicone tube installation

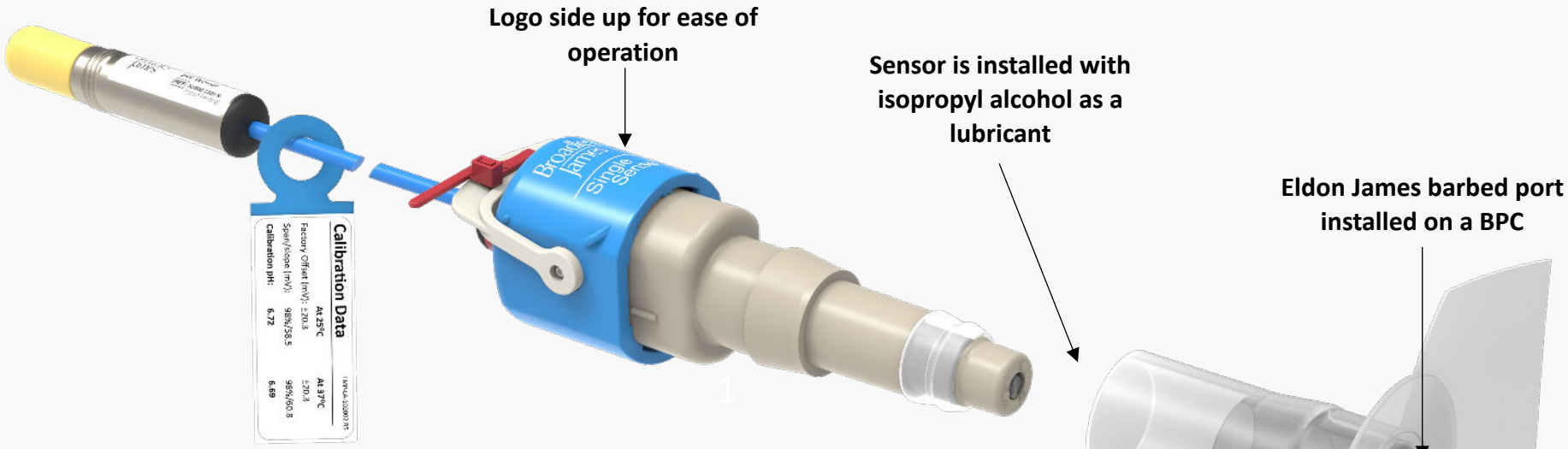
2.3 Remove the protective end cap.



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.

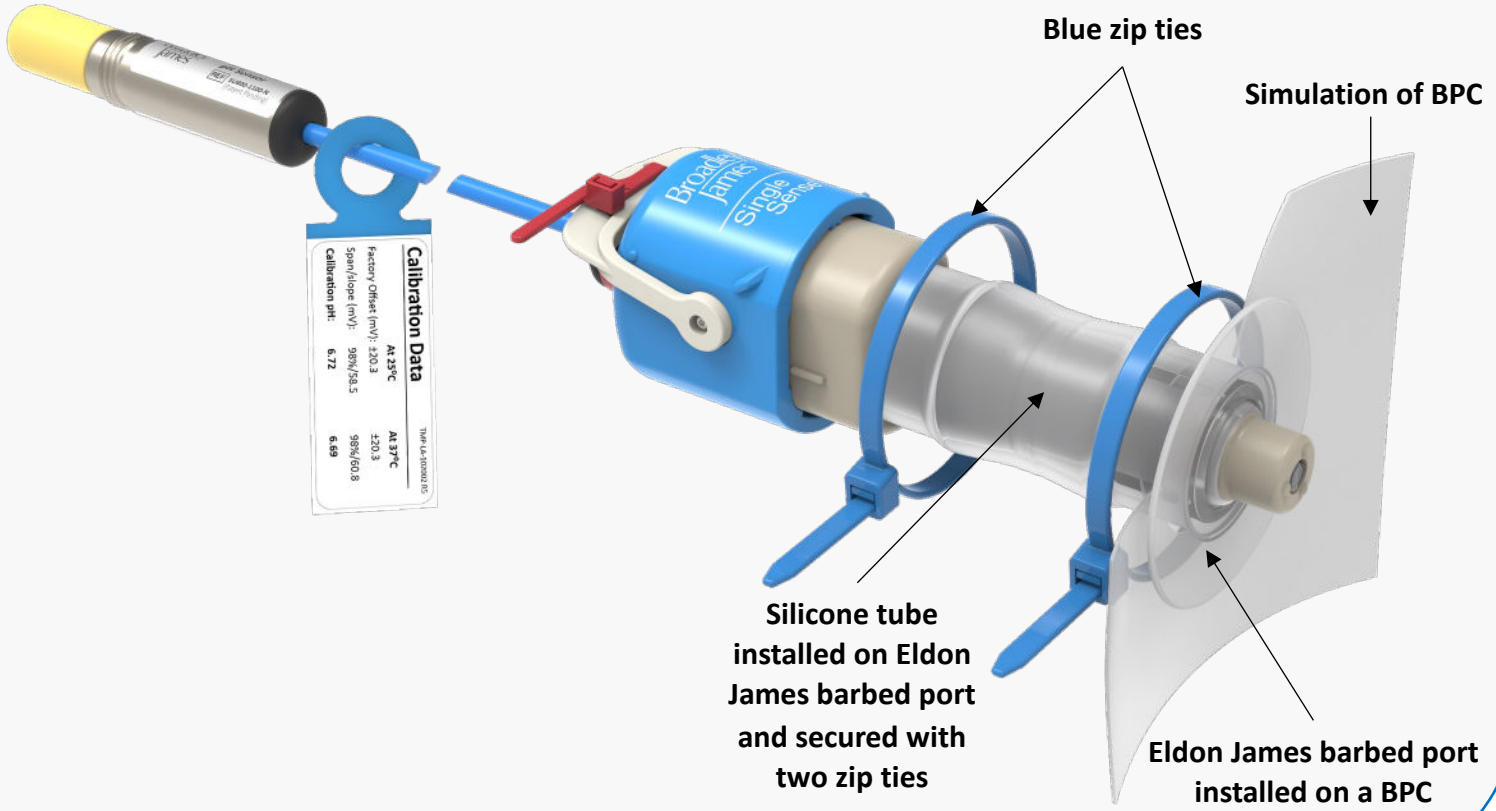


Figure 8. Zip tie placement

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.

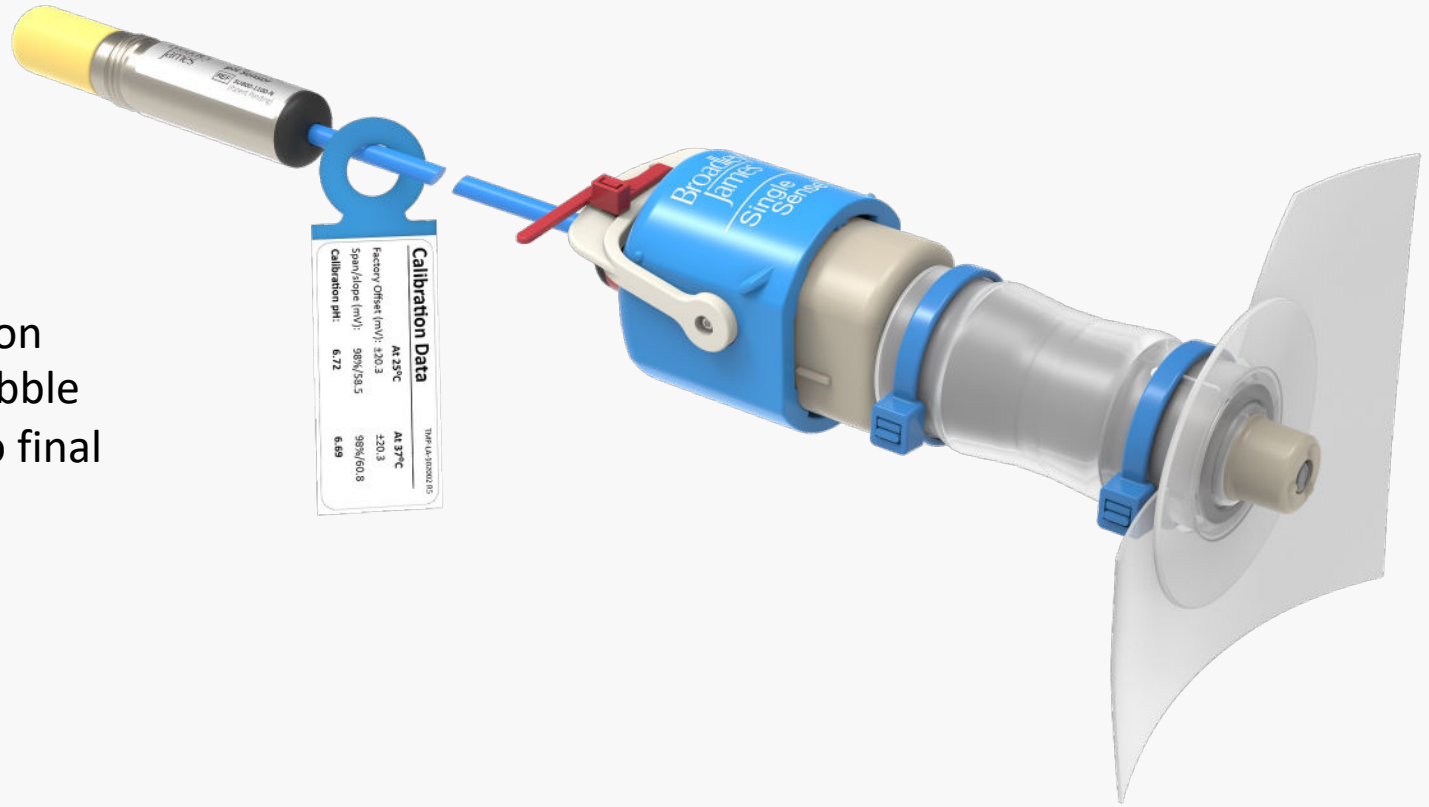
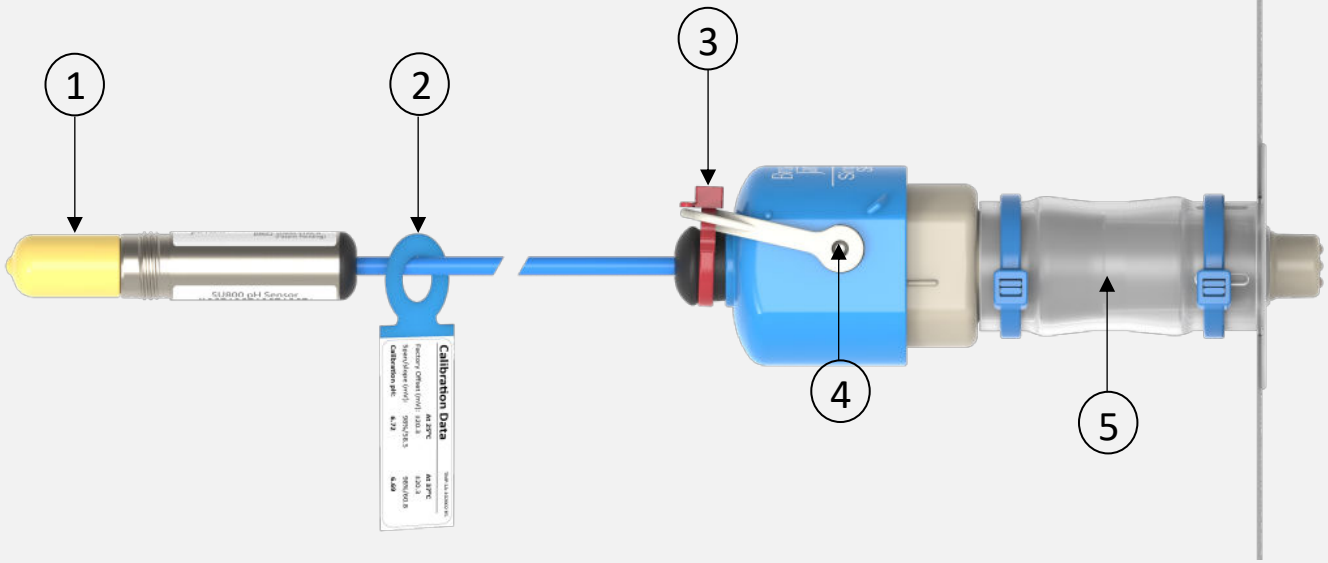


Figure 9. Sensor final installation

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 E – Specification Sheet
- Appendix F – Purchasing Sheet

Appendix A – Dimensional Drawing of Installed Sensor

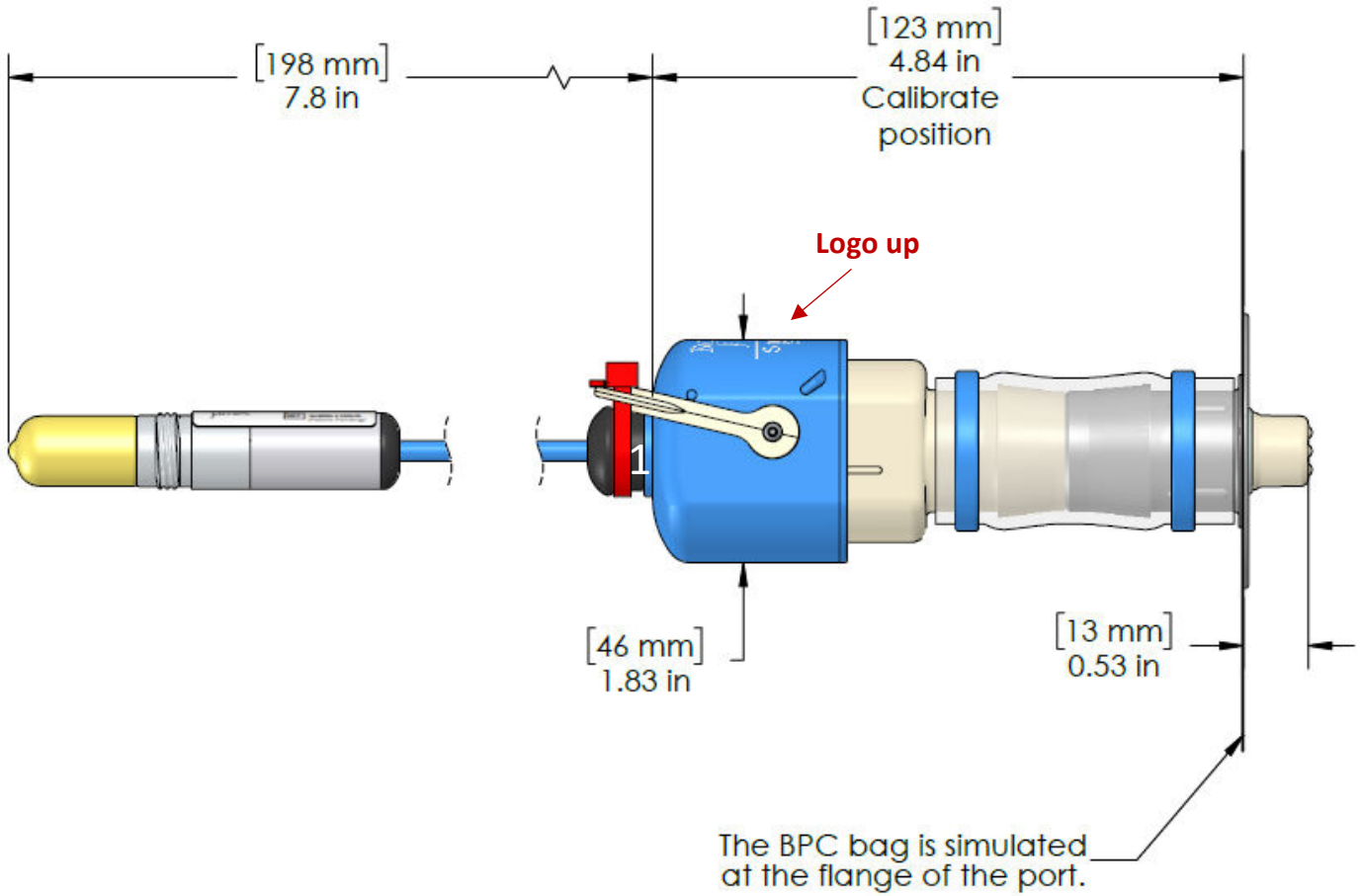
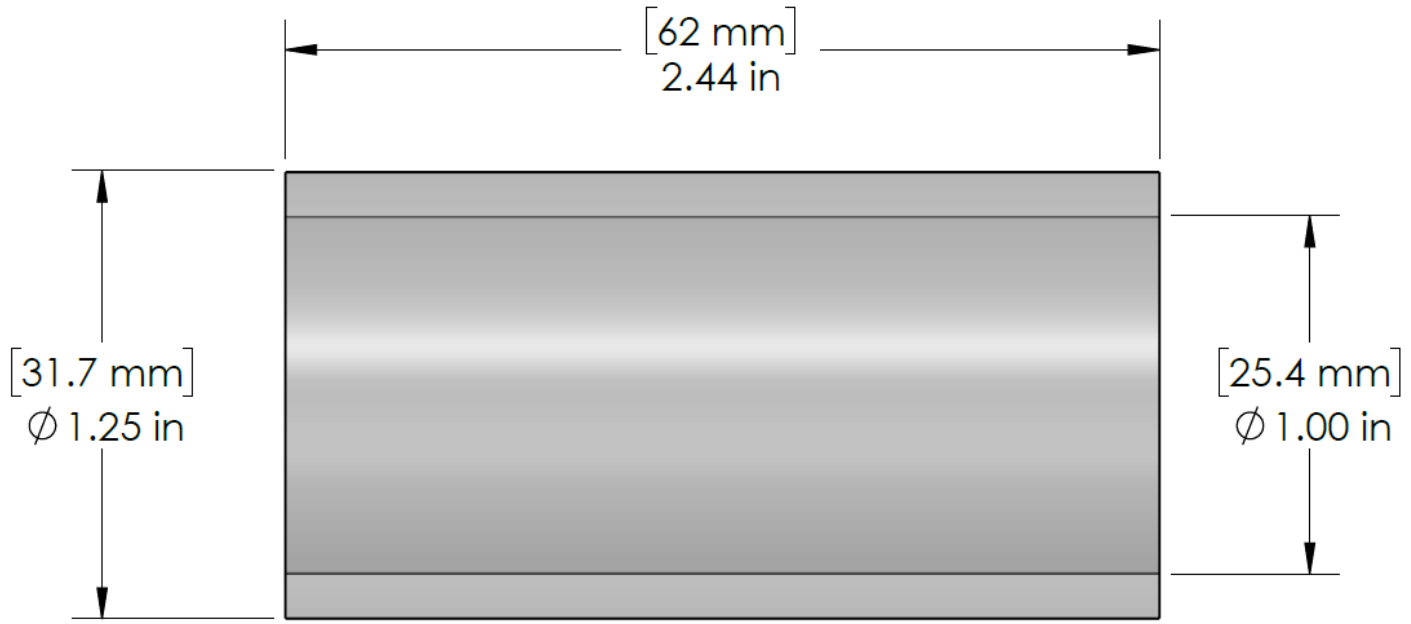


Figure 11. Dimensional drawing of sensor

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]

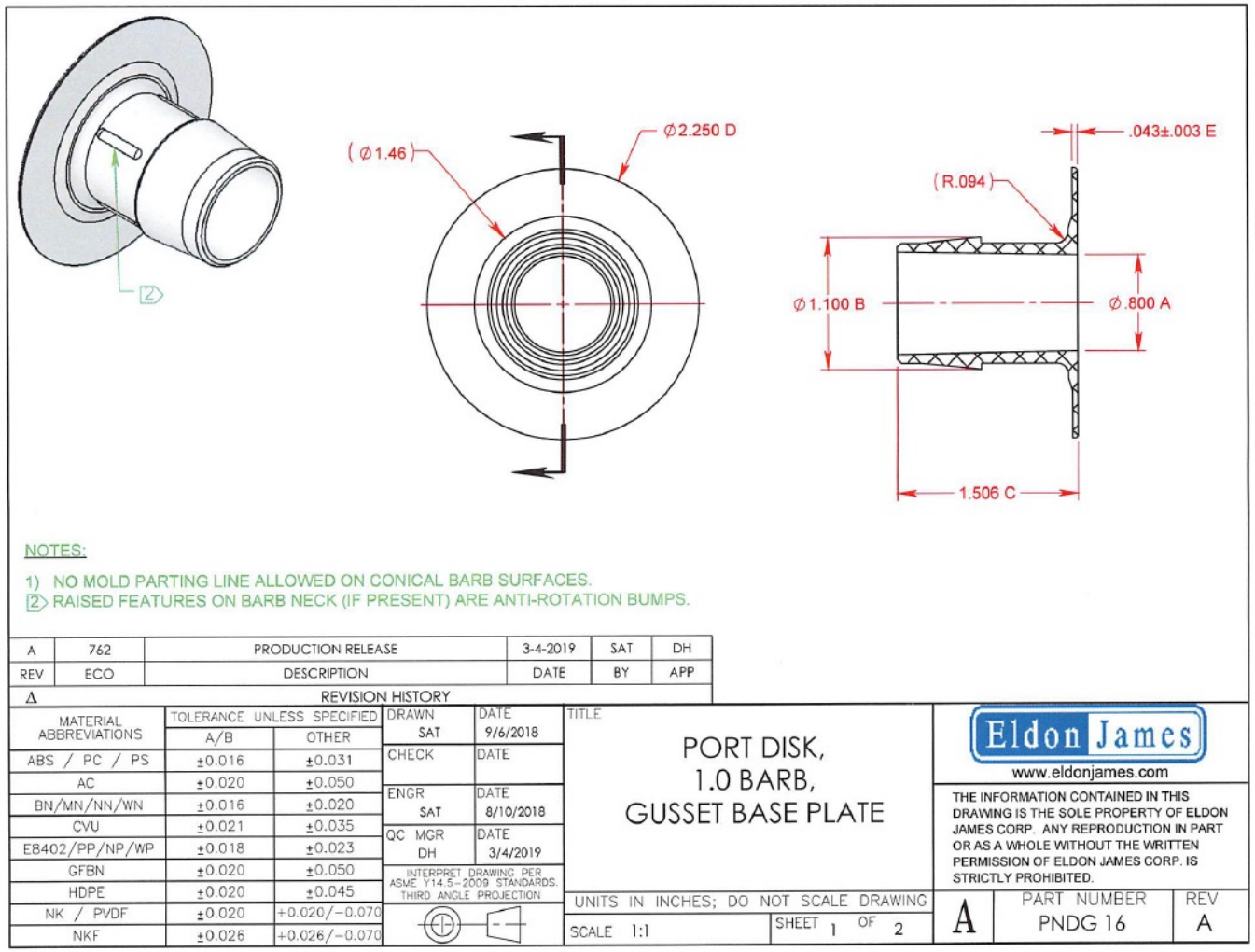


Figure 13. Dimensional drawing of barbed port

[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.

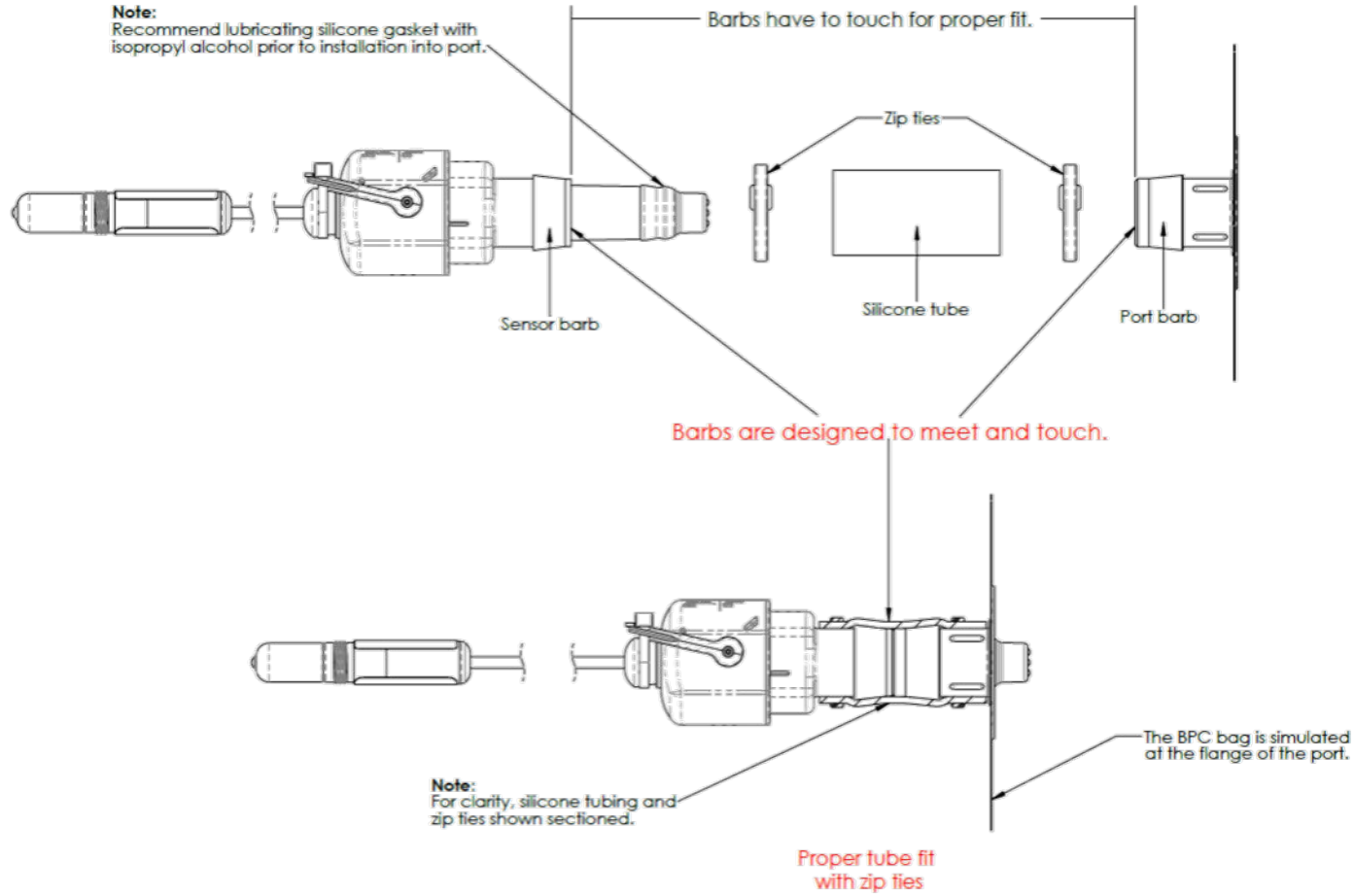


Figure 14. Dimensional drawing of tubing fit

Appendix E – Specification Sheet (Model SU800)

Product Specification Sheet
Doc Nbr: PSS-062101 R6
April 2024 – Page 1

REF SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Description

The SU800-16-V8 SingleSense® Single-Use pH Sensor is a gamma sterilizable and designed with a 1-inch hose barb for pre installation into a bioprocess container (BPC). The sensor can be used for upstream and downstream BPC applications including media mixing, buffer preparation, and large-scale cell culture bioreactors.

Rugged and always ready to use, no hydration time is required. The sensor can be installed horizontally and retracted during mid-run for a 1-point standardization check with the built-in buffer storage chamber.

Model	SU800
Part Number	SU800-16-V8

SU800-16-V8 Single-Use pH Sensor

Sensor Specifications

Measurement Range	2–12 pH
Operational Temp. Range	15°–40° C [60°–104° F]
Storage Temperature	5°–35° C [41°–95° F]
Shipping and Transportation	-29° C [-20° F] for up to 72 hours
Shelf Life	36 months Post Gamma: 30 months
Gamma Tolerance Level	50 kGy
Sensor/Tubing Interface	1 inch Hose Barb
Sensor Connector Cable	8-pin Variopin

Wetted Materials

Main Sensor Body	PEEK, USP 88 Class VI, USP 87, ADI Free
Port Gasket	Dimethyl Silicone Rubber Pt Cure, USP 88 Class VI, USP 87, ADI Free
O-ring	EPDM, USP 88 Class VI, USP 87, FDA Compliant Extraction Tested 21 CFR, 177.2600, ADI Free
pH Glass Electrode	Lead-free Glass
Ceramic Junction	Alumina Silicate

Features

- pH sensor retracts into the buffer storage chamber in the sensor body for long-term storage
- Sensor can be inserted and retracted multiple times without loss of buffer storage electrolyte

Benefits

- Sensor can be stored and protected in sensor housing until needed
- Always ready to use, no rehydration time required
- Sensor can be retracted into buffer storage chamber during mid-run for 1-point standardization check

PATENTED
EU PATENT 3064905

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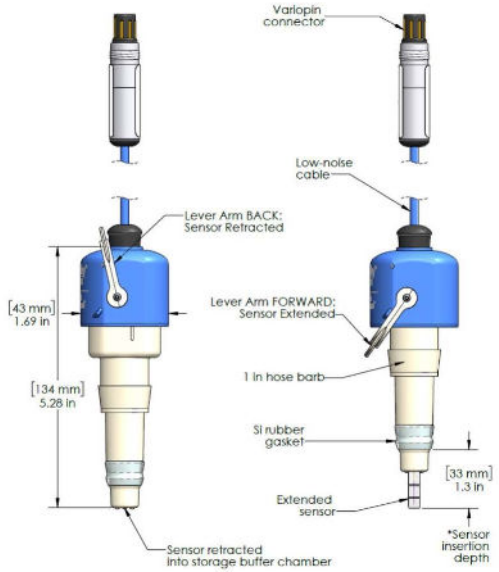
Product Specification Sheet
Doc Nbr: PSS-062101 R6
April 2024 – Page 2

REF SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Dimensional Drawings of SU800-16-V8



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Appendix F – Purchasing Sheet (Model SU800)

Product Purchasing Sheet
Doc Nbr: PDS-112007 R8
April 2024 – Page 1

REF SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Description

The SU800-16-V8 SingleSense® Single-Use pH Sensor is designed for horizontal preinstallation in a bioprocess container (BPC) with subsequent gamma sterilization.

Purchase Information

Part Number	SU800-16-V8
Description	Single-Use pH Sensor for pre-install in BPC

Classification

Model Type	SU800
Product Type	pH Sensor

Specifications

Measurement

Type	pH
Principle	Potentiometric
Range	2–12 pH
Drift	≤ 0.01 pH per day
Accuracy	± 0.5 pH units

Operational Range

Temperature	15°–40° C [60°–104° F]
Pressure	0–778 mm Hg [0–15 psig]
Flow Rate	Not applicable

Signal

Input	Not applicable
Output	Sensor: ±414 mV

Sterilization

Autoclavable	Not autoclavable
Steam Sterilizable	Not steam sterilizable
Gamma Sterilizable	Yes, up to 50 kGy

Connectors and Cables

Connector	8-pin Variopin
Cable Length	0.15 m [6 inches]

Process Interface

Insertion Method	1-inch Hose Barb
Insertion Length	13 mm when retracted, 33 mm when extended

SU800-16-V8 Single-Use pH Sensor

Wetted Materials

PEEK, USP 88 Class VI, USP 87, ADI-Free
Extraction Tested 21CFR, 177.2600 Dimethyl Silicone Rubber, Pt Cure, USP 88 Class VI, USP 87
Extraction Tested 21CFR, 177.2600 EPDM USP 88 Class VI, USP 87
FDA Compliant, ADI-Free Lead-Free Glass, Alumina Silicate

PATENTED
EU PATENT 3684905

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Product Purchasing Sheet
Doc Nbr: PDS-112007 R8
April 2024 – Page 2

REF SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Packaging and Regulations

Packaging Information

Package Type	Cardboard box with double-bagged sensor inside
Package Dimensions	30.48 x 30.48 x 5.08 cm [12 in x 12 in x 2 in]
Package Weight	< 0.5 kg [1 lb]
Double Bagged	Yes, sensor is double-bagged
Cleanhood Bagged	Yes, inner bag only
Cleanhood Class	Class 7 Clean Air Hood
Storage Conditions	Temperature: 5°–35° C [41°–95° F]
Shipping and Transportation	Temperature: -29° C [-20° F] for up to 72 hours
Included Accessories	Not applicable
Quality Certificate	Included
Shelf Life	36 months
Shelf Life Post Gamma Sterilization	30 months

Origination and Tariff Code

Harmonized Tariff Trade Code	9027803100
Country of Origin	USA
MFR Location	California, USA

Purchasing Information

Unit of Sale	Each
Minimum Purchase Quantity	Each

Regulatory and Compliance

CE Compliant	Yes
RoHS Compliant	Yes
REACH Compliant	Yes
CFR 21 11 Compliant	Not applicable
BSE/TSE/ADI Free	Yes
USP 88 Class VI, USP 87 Compliant	Yes, all wetted parts
FDA Material Compliant	Yes, all wetted parts

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