



July xx, 2021

URGENT: FIELD SAFETY NOTICE
AQUABEAM® Handpiece (REF HP2000)

Customer Name
Hospital Name
Street Address
City, State, Zip Code

Dear Valued PROCEPT Customer:

At PROCEPT BioRobotics Corporation ("PROCEPT"), providing high quality, safe and effective products is our top priority. The purpose of this letter is to inform you that PROCEPT is voluntarily recalling eight (8) specific lots of our AQUABEAM® Handpiece (REF HP2000, hereafter referred to as "Handpiece"), which is a single-use component of the AQUABEAM® Robotic System used to perform Aquablation therapy. Our records indicate that affected devices have been shipped to your account.

Reason for the Voluntary Recall:

PROCEPT has identified that the scope tube tip may detach from the telescoping tube in specific lots of our Handpiece. This detachment may occur by the forces that occur either before insertion into the patient during preparation, or after insertion into the patient during the treatment planning stage of the Aquablation procedure.

To date, we are aware of seven (7) complaints due to this specific failure mode. There have been no reports of any patient injury or adverse health consequences due to this issue.

Steps to perform if this occurs:

If the scope tube tip detaches from the telescoping tube before insertion into the patient during preparation, the Handpiece must be replaced with a new Handpiece.

If the scope tube tip detaches after the Handpiece has been inserted into the patient, this is seen cystoscopically and the Handpiece must be removed and replaced with a new Handpiece. In the event that the scope tube tip separates from the Handpiece entirely, the scope tube tip may fall into the bladder or the prostate. The standard 26Fr resectoscope, used in an Aquablation procedure, will accommodate the removal of the detached scope tube tip.

Risk to Health:

The most common and foreseeable consequence identified in the complaints is a clinically minor procedural delay due to the need to exchange the defective Handpiece for a new Handpiece.

In the event, that the scope tube tip separates from the Handpiece and falls into the bladder or prostate and needs to be removed, a clinically minor procedural delay will occur to remove the scope tube tip and exchange the defective Handpiece for a new Handpiece.

Note: There is no risk to patients that have already been successfully treated with an AQUABEAM Handpiece from these affected lots.



Affected Product and Lot Information:

Our records indicate that your facility received some of the affected product. The table below provides a complete list of all affected products. Please note that only the devices listed below are affected.

Device Name	Model	Lot Number(s)
AQUABEAM Handpiece	HP2000	21C00226; 21C00290; 21C00304; 21C00359; 21C00373; 21C00464; 21C00465; 21C00527

Actions to be taken by you:

1. Please read this notice.
2. **Please use stop using the affected lots of Handpieces** that have been listed in this notice.
3. **Please remove the affected lots of Handpieces from your regular inventory location and segregate them for future return and replacement.**
4. **Please complete the attached Voluntary Recall Acknowledgement Form even if you do not have any affected product.**
5. Please pass along this notice to all those who need to be aware of it within your organization.
6. Once the Voluntary Recall Acknowledgement Form is received by PROCEPT, we will provide instructions on how to return the affected Handpieces to PROCEPT and will advise you of an approximate time you will receive replacement Handpieces.

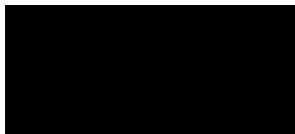
Actions Being Taken by PROCEPT BioRobotics:

PROCEPT is conducting a detailed failure investigation for this issue and has linked the likely root cause to a purchased component. The defect has only been observed with a specific lot of the purchased component. We are in the process of implementing appropriate corrective actions to prevent recurrence of the reported failure mode.

All applicable competent authorities are being notified of this action.

PROCEPT BioRobotics considers patient safety and customer satisfaction our top priorities. We sincerely regret any inconvenience this action may cause your operations. If you have any questions, please feel free to contact your local Aquablation Clinical Specialist, Sales Representative, or PROCEPT Customer Service by telephone at +1.650.232.7222 or e-mail cs@procept-biorobotics.com.

Sincerely,



Vice President, Regulatory Affairs & Quality Assurance



Immediate Attention Requested

Field Safety Notice Acknowledgement Form for: AQUABEAM® Handpiece (REF HP2000)

This Field Safety Acknowledgment Form relates to and is intended to be completed in connection with the field safety notice of eight (8) lots of the AQUABEAM Handpiece (“Handpiece”) provided on **xx July 2021**. The lot numbers listed below identify the lots that are subject to this notice. **Please audit your physical inventory and to identify the quantity, if any, of Handpieces of each affected lot number, and please check the appropriate box below:**

- A thorough search for all affected lots has been completed and no inventory of Handpieces with the Lot Numbers listed below exists.
- A thorough search for all affected lots has been completed and the following quantities of affected Handpieces have been quarantined and will be returned to PROCEPT BioRobotics
 - **RGA Number:** _____
 - To obtain a Returned Goods Authorization (RGA) Number, contact your local Aquablation Clinical Specialist, Sales Representative, or PROCEPT Customer Service by telephone at +1.650.232.7222 or via e-mail to cs@procept-biorobotics.com.

Product Name and Code: AQUABEAM Handpiece, REF HP2000

Lot Number	Quantity
21C00226	
21C00290	
21C00304	
21C00359	

Lot Number	Quantity
21C00373	
21C00464	
21C00465	
21C00527	



Lot number information

By signing this form, I confirm that I have read and understand the instructions provided in the Field Safety Notice and this form. Please print legibly.

Signature: _____

Institution: _____

Print Name: _____

Telephone: _____

Title: _____

Email: _____

Date: _____

Please return a completed, signed form to PROCEPT BioRobotics Customer Service as instructed below:

1. Fax this completed form to +1.888.285.3777 or send a scanned copy via e-mail to cs@procept-biorobotics.com
2. Return a copy of this completed form with the returned product.

For PROCEPT BioRobotics Use Only.

Received by: _____

Date: _____