

URGENT: MEDICAL DEVICE RECALL
MicroClave Incomplete Assembly
See Table 1 for Affected Product and Lot Numbers

01 August 2022

Dear Valued Customers:

Director of Risk Management
Director of Nursing
Director of Materials Management

ICU Medical, Inc. is issuing this Urgent Medical Device Recall letter to notify you of a potential defect with the MicroClave Clear connector. This letter details the issue and the required steps for you to perform.

Issue:

ICU Medical has identified the potential for a manufacturing defect within specific lots of MicroClave Clear sets, which may result in a visible gap between the MicroClave Clear connector's top and bottom housings.

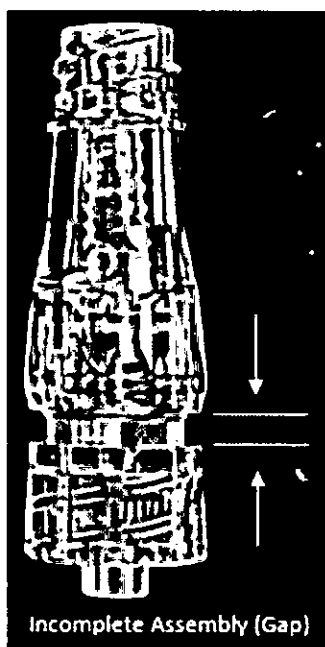
Potential Risk:

Inadequate connection between the MicroClave Clear connector's top and bottom housings may potentially cause or lead to delayed delivery of infusion solution during setup/infusion, fluid leak, blood loss/exposure to patient blood, air embolism, exposure to allergenic/caustic substances, or fluid path contamination. To date, ICU Medical has not received any reports of serious injury or death associated with this issue.

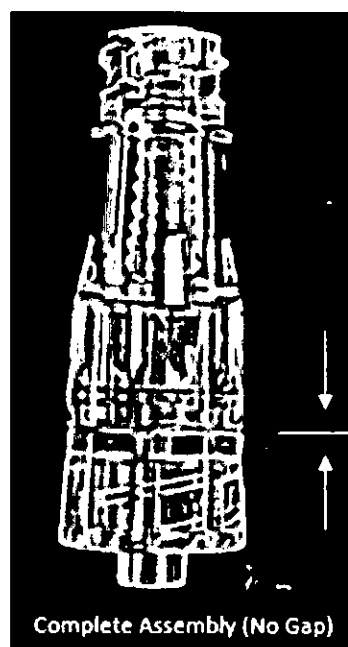
Affected Product:

Our records indicate that you may have received some of the affected products, which were distributed in the United States between December 2021 and March 2022. The affected item and lot numbers are provided in Table 1.

The images below depict a MicroClave Clear connector with a visible gap versus a MicroClave Clear connector with no gap:



Picture 1 with Gap



Picture 2 with No Gap

Required Actions for Users:

- 1) Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility.
- 2) Inform potential users of the product in your organization of this notification and complete the attached response form. Return the completed response form to the fax number or e-mail address on the form, even if you do not have the affected product.
- 3) Return affected product using the return label provided with this letter. Contact Sedgwick at 1-888-965-5798 (M-F, 8am-5pm ET) if you have not received a return label or require additional labels for returning the affected product. The return labels are for single use only. Please do not reproduce. Please visit <http://expertezlabel.com> to request additional labels for returning affected product. To ensure proper and timely credit, follow the instructions on the return label for returning product. Upon receipt of the completed response form and return of the affected product, ICU Medical will credit you for any product returned. You will only receive credit for product that you return. NOTE: Credits for product purchased through distributor will be credited by the distributor.
- 4) If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product / Table 1 sections of this notification and ask them to contact Sedgwick at 1-888-965-5798 (M-F, 8am-5pm ET) to obtain a response form.

Follow up Actions:

Please contact Customer Service using the information provided below for assistance reordering replacement product.

For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	1-866-829-9025, option 8 or customerservice@icumed.com (M-F, 8am-6pm CT)	Additional information or assistance

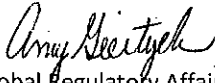
The U.S. Food and Drug Administration (FDA) has been notified of this action. Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

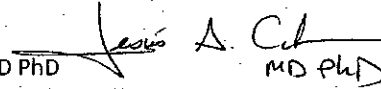
ICU Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Amy Giertych
Vice President, Global Regulatory Affairs



Jesus Cabrera, MD PhD
Medical Director, Medical Affairs



Enclosures:

- Affected Product and Lot Numbers
- Response Form
- External FAQs

Table 1: Affected Product and Lot Numbers

List Number	Product Description	Lot Number	
011-MC100	MicroClave™ Clear Connector	5737404 5740712	5740719 5793259
011-MC33538	Appx 0.36 ml, 3-Way Stopcock w/MicroClave® Clear, Rotating Luer	5772700	
12512-01	MicroClave™ Clear Neutral Connector	5724458 5736445 5739485 5739486 5739488 5754899	5771934 5793264 5798239 5802842 5812522
12517-01	7" (18 cm) Appx 0.31 ml, Smallbore Pressure Infusion (400psig) Ext Set w/Remv MicroClave™ Clear, Purple Clamp, Rotating Luer	5735675 5755784	5755788 5812525
A1009	7" (18cm) Appx 0.31 ml, Smallbore Ext Set w/Remv MicroClave® Clear, NanoClave® T-Connector, Clamp, Rotating Luer	5747112	
A1099	6.5" (16.5 cm) Appx 0.31 ml, Smallbore Pressure Infusion (400psig) Ext Set w/Remv MicroClave® Clear, NanoClave® T-Connector, Purple Clamp, Rotating Luer	5692378	
A1129	7" (18 cm) Appx 0.31 ml, Smallbore Pressure Infusion (400psig) Ext Set w/Remv MicroClave® Clear, Clamp, NanoClave® T-Connector (Purple Ring), Rotating Luer	5755485 5772087	
A1132	7" (18 cm) Appx 0.31 ml, Smallbore Pressure Infusion (400psig) Ext Set w/Remv MicroClave® Clear, Purple Clamp, NanoClave® T-Connector (Purple Ring), Rotating Luer	5772482	
A1152	7" (18 cm) Appx 0.32 ml, Smallbore Pressure Infusion (400psig) Ext Set w/Remv MicroClave® Clear, NanoClave®, Purple Clamp, Luer Lock	5735432 5787700	
AC235	14"(36cm)Appx3.0ml, Trifuse Ext Set w/3 MicroClave Clear™, 3 BCV,4-Way NanoClave™ Stopcock(Red Ring)	5782946	
CH3771	6.5 IN (17 cm) APPX 0.78ml, EXT SET w/Clave CLEAR, Clave 4-Way Stopcock, Spiros, RED CAP	5782919	
MB4V01	MicroClave® Multi-Dose Vial Access Spike, Approx Priming Volume: 0.16 mL	5797658	
MC100	MicroClave™ Clear Neutral Connector	5716986 5716988 5716989 5716992 5716993 5737649 5737651 5739477 5739478 5739482	5739484 5739493 5755652 5757426 5771936 5771950 5771956 5786565 5815050
MC100-PR	MicroClave™ Clear Connector w/ Purple Ring	5738352	
MC330073	7" (18 cm) Appx 0.99 ml, Ext Set w/2 MicroClave™ Clear, Check Valve, Clamp, Rotating Luer	5724537	
MC330113	7.5" (19 cm) Appx 0.52 ml, Smallbore Bifuse Pressure Infusion (400psig) Ext Set w/2 Remv MicroClave™ Clear, 2 Purple Clamps, Rotating Luer	5746371 5755711 5789359	
MC330246	8.5" (22 cm) Appx 0.85 ml, Bifuse Pressure Infusion (400 psig) Ext Set w/2 Remv MicroClave™ Clear, 2 Purple Clamps, Rotating Luer	5641882 5738474 5773798	5788509 5809713
MC330247	8" (20 cm) Appx 0.56 ml, Smallbore Bifuse Pressure Infusion (400 psig) Ext Set w/2 Remv MicroClave™ Clear, 2 Purple Clamps, Rotating Luer	5745619 5756766	5777168 5789411

MC330255	7.5" (19 cm) Appx 0.85 ml, Ext Set w/Remv MicroClave® Clear, MicroClave® Clear, Clamp, Rotating Luer	5712884	
MC3302R	7" (18 cm) Appx 0.3 ml, Smallbore Ext Set w/Remv MicroClave™ Clear, Clamp, Rotating Luer	5745628	
MC330362	72" (183 cm) Appx 1.4 ml, Smallbore Ext Set w/MicroClave™ Clear, Anti-Siphon Valve, Clamp, Luer Lock	5772361	
MC330417	10 IN (25cm) APPX 2.3ml, TRIFUSE EXT, 3 MicroClave Clear (1 Remv w/RED RING)	5782954 5816260	
MC330446	8" (20 cm) Appx 0.79 ml, Smallbore Trifuse Ext Set w/3 Remv MicroClave® Clear, 3 Clamps (Yellow, Blue, Green), Luer Lock	5746457	
MC330476	6.5" (17 cm) Appx 0.84 ml, Smallbore Bifuse Ext Set w/2 MicroClave® Clear, 2 Check Valves, Luer Lock	5677797 5692512	5721748
MC330545	111" (282 cm) Appx 7.4 ml, Transfer Set w/MicroClave® Clear, Dual Check Valve, Smallbore Bifuse Ext Set w/MicroClave® Clear, 3 Clamps (2 Red, White), Rotating Luer	5773182	
MC33056	7" (18 cm) Appx 0.70 mL Pressure Infusion (400psig) Ext Set w/Remv MicroClave™ Clear, Purple Clamp, Rotating Luer	5772683	
MC330583	102" (259 cm) Appx 5.0 ml, Transfer Set w/MicroClave™ Clear, Dual Check Valve, Smallbore Trifuse Ext Set w/2 MicroClave™ Clear, 0.2 Micron Filter, Clamp, Rotating Luer	5773172	
MC330605	11" (28 cm) Appx 0.83 ml, Pressure Infusion (400 psig) Ext Set w/2 MicroClave™ Clear (1 Remv), Purple Clamp, Rotating Luer w/Filter Cap	5789539	
MC330611	125 IN (318 cm) APPX 23.8 ml, 10 Drop, 2 MicroClave Clear, 2 STOP W/2 MicroClave Clear	5825526 5850314	
MC330615	106" (269 cm) Appx 5.4 ml, Transfer Set w/MicroClave™ Clear, Dual Check Valve, 3 Clamps (2 White, Green), Rotating Luer	5773186 5776699	
MC33087	Tri-Connector w/2 MicroCLAVE CLEAR, ROTATING LUER	5732851 5757039	
MC33092	6 IN(15cm)APPX 0.64ml, SMALLBORE TRIFUSE,3 Remv MicroCLAVE CLEAR	5757043	
MC33119	4" Smallbore Bifuse Ext Set w/2 Remv MicroClave® Clear, 2 Clamps, Rotating Luer	5692600 5725019	5777549
MC33122	7" (18 cm) Appx 0.45 ml, Pressure Infusion (400psig) Ext Set w/Remv MicroClave® Clear, Purple Clamp, Rotating Luer	5757061 5772640	
MC33196	7 IN (18cm)APPX 0.96ml, SMALLBORE TRIFUSE, REMV 3 MicroClave Clear, 3 BCV	5823306	
MC33213	7" (18 cm) Appx 0.31 ml, Smallbore Pressure Infusion (400psig) Ext Set w/Remv MicroClave® Clear, Purple Clamp, Rotating Luer	5736601 5789780	5789784
MC3325	7" (18cm) Appx 0.69mL Ext Set w/Remv MicroClave™ Clear, Clamp, Rotating Luer	5772606 5772609	5772630
MC33290	4 IN(10cm)APPX 0.65ml, SMALLBORE QUADFUSE SET, 4 Remv MicroClave CLEAR	5786080 5816255	
MC33312	26 IN (66cm) APPX 1.7ml, SMALLBORE TRIFUSE, 3 MicroClave CLEAR, 3 BCV, FILTER	5782876 5823287	
MC33326	7" (18 cm) Appx 0.43 ml, Pressure Infusion (400psig) Ext Set w/Remv MicroClave™ Clear, Rotating Luer	5757376 5772627	5772638 5810377
MC33337	8 IN(20 cm) APPX 0.99ml, SMALLBORE TRIFUSE, MicroClave Clear, FILTER	5753046	
MC33343	15 IN(38cm)APPX 0.53ml, SMALLBORE SET, REMV MicroClave CLEAR	5762347	
MC33348	9IN(23cm)APPX 0.55ml, SMALLBORE BIFUSE, 2 MicroClave CLEAR	5753060 5762355	5789832
MC33409	5 IN(13cm)APPX 0.59ml, SMALLBORE TRIFUSE, 3 REMV MicroClave CLEAR	5746703 5753968	
MC33424	60" (152cm) Appx 0.43 ml, SMALBORE Ext Set w/Remv MicroClave® Clear, Clamp, Luer Lock	5778865 5789733	

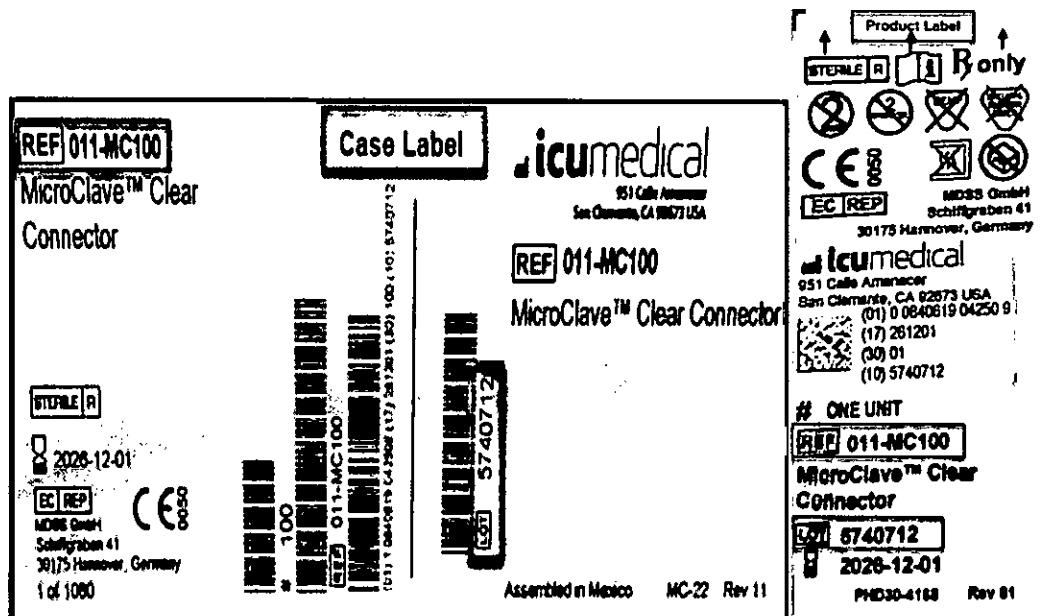
MC33425	60" (152 cm) Appx 0.80 ml, Smallbore Ext Set w/Remv MicroClave® Clear, 0.2 Micron Filter, Clamp, Luer Lock	5737011 5773212	5778871
MC33482	6 IN(15cm)APPX 1.3ml, QUADFUSE SET, 5 MicroClave CLEAR, 2 T-CONN	5785919	
MC33492	14" (36cm) Appx 0.47 ml, Smallbore Ext Set w/Remv MicroClave® Clear, Clamp, Luer Lock	5754132 5772548	5778966
MC33493	9" (23 cm) Appx 0.45 ml, Smallbore Bifuse Ext Set w/2 MicroClave® Clear (1 Remv), 2 Clamps, Luer Lock	5684445	
MC33547	6 IN(15cm)APPX 1.2ml, SMALLBORE TRIFUSE, 3 MicroClave Clear, FILTER	5753321	
MC33563	60" (152 cm) Appx 1.8 ml, Smallbore Ext Set w/Remv MicroClave® Clear, Clamp (Blue), Luer Lock	5737877 5800935	
MC33600	7" (18 cm) Appx 0.27 ml, Pressure Infusion (400 psig) Smallbore Ext Set w/Remv MicroClave® Clear, Clamp (Blue), Luer Lock	5789950	
MC33632	5" (13cm) Appx 0.28ml, Smallbore Ext Set w/MicroClave® Clear, T-Connector Inj Site, Clamp, Luer Slip	5737895	
MC33667	7.5" (19 cm) Appx 0.50 ml, Smallbore Bifuse Ext Set w/2 Remv MicroClave® Clear, 2 Clamps, Rotating Luer	5685338	
MC33670	87" (221cm) Appx 2.8 ml, Smallbore Trifuse Ext Set w/MicroClave® Clear, 0.2 Micron Filter, 4 Clamps, Rotating Luer, 2 Exts, Drop-In MicroClave® Clear	5712886	
MC33671	80" (203 cm) Appx 2.5 ml, Smallbore Trifuse Ext Set w/Remv MicroClave® Clear, 0.2 Micron Filter, 4 Clamps, Rotating Luer, 1 Ext, Drop-In MicroClave® Clear	5712863	
MC33729	7" (18 cm) Appx 0.73 ml, Pressure Infusion (400psig) Bifuse Ext Set w/2 Remv MicroClave™ Clear, 2 Purple Clamps, Luer Lock	5789984 5800993	
MC33786	7" (18 cm) Appx 0.30 ml, Smallbore Pressure Infusion (400psig) Ext Set w/Remv MicroClave® Clear, Clamp, Rotating Luer	5778247	
MC33795	8.5" (22 cm) Appx 0.68 ml, Smallbore Trifuse Ext Set w/3 MicroClave® Clear (1 Remv), 3 Clamps, Rotating Luer	5712882 5778251	
MC33917	7 IN(18 cm)APPX 0.73ml, SMALLBORE TRIFUSE SET, REMV 3 MicroClave Clear	5757508	
MC33980	7 IN (18cm) APPX 1.1ml, BIFUSE EXT SET, 2 MicroClave Clear 1 REMV	5757494 5762677	
MC33981	4" (10 cm) Appx 0.45 ml, Smallbore Trifuse Ext Set w/3 MicroClave® Clear (1 Remv), 3 Clamps, Rotating Luer	5778306 5800052	
MR4001	MicroClave™ Clear Neutral Connector, Approx Priming Volume: 0.04 mL	5738132	
MS984	MicroClave™ Clear Connector	5737492	
SC137	60 IN(152cm) APPX 0.85ml, SMALLBORE, CLAVE STOPCOCK, MicroCLAVE CLEAR	5773207	
SC3000	MicroClave™ Clear Neutral Connector	5726857 5753967	
Z3419	8" (20cm) APPX 0.56ml, Smallbore Pressure Infusion (400psig) Bifuse Ext Set w/2 MicroClave® Clear, 2 Purple Clamps, Rotating Luer	5754551	
Z3420	8 IN(20cm)APPX 0.37ml, SMALLBORE BIFUSE, 2 MicroCLAVE CLEAR	5773199	
Z3429	20 IN (51cm) APPX 4.1 ml, EXT SET, STOPCOCK wMicroCLAVE CLEAR	5749820 5825452	
Z3523	6 IN(15cm) APPX 0.75ml, SMALLBORE TRIFUSE, 3 REMV MicroCLAVE CLEAR	5788233	
Z3574	33 IN(84cm)APPX 1.1ml, SMALLBORE SET, MicroCLAVE CLEAR, BCV	5745063 5776728	
Z3678	8" (20 cm) Appx 0.61 ml, Pressure Infusion (400psig) Ext Set, MicroClave® Clear, Clave® Clear, 2 Purple Clamps, Rotating Luer	5754702 5777801	

MicroClave Incomplete Assembly

Urgent: Medical Device Recall Frequently Asked Questions

ICU Medical is issuing a medical device recall letter informing affected customers of a potential defect with the MicroClave Clear connector. As a part of this notification, ICU Medical is notifying each affected customer and authorized distributor of this issue.

1. **Q What is the issue?**
ICU Medical has identified the potential for a manufacturing defect within specific lots of MicroClave Clear sets, which may result in a visible gap between the MicroClave Clear connector's top and bottom housings.
2. **Q What is the potential risk?**
Inadequate connection between the MicroClave Clear connector's top and bottom housings may potentially cause or lead to delayed delivery of infusion solution during setup/infusion, fluid leak, blood loss/exposure to patient blood, air embolism, exposure to allergenic/caustic substances, or fluid path contamination. To date, ICU Medical has not received any reports of serious injury or death associated with this issue.
3. **Q What devices are affected?**
Refer to Table 1 of the Urgent Medical Device Recall notice for the impacted products and lot numbers.
4. **Q How can customers identify if which devices need corrective action?**
The list number and lot number are printed on every box and individual packaging. Refer to below example:



5. **Q Have there been any complaints related to this issue?**
No.
6. **Q Has there been any patient harm related to this risk?**

No. To date, ICU Medical has not received any reports involving a serious injury or death related to this issue.

7. Q What action is ICU Medical taking?

ICU Medical is notifying affected customers via the attached letter and requiring removal of the affected products from the market.

8. Q Can devices at my facility continue to be used?

Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility.

Please follow the instructions provided in the customer letter to return your affected products.

9. Q How is the customer communication sent?

The notifications are being sent to the Director of Risk Management, Director of Nursing, and Director of Materials Management at each facility. Each customer and distributor will receive a letter, response card, and return label via courier.

10. Q Is the information available online?

Yes. The letter and FAQs distributed in the US can be found on ICU Medical's website at <http://www.icumed.com/support/customer-communications.aspx>

11. Q Is this a voluntary action?

Yes. ICU Medical is voluntarily taking this action.

12. Q Should I return affected products?

Yes. As communicated in the attached Urgent Medical Device Recall notice, you should discontinue use and distribution of the affected product immediately. You should also check your inventory and quarantine all affected product at your facility.

13. Q How do I order replacement product?

Please contact Customer Service using the information provided below for assistance reordering replacement product.

14. Q Has FDA been notified?

Yes.

15. Q Where can I find more information?

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	1-866-829-9025, option 8 or customerservice@icumed.com (M-F, 8am-6pm CT)	Additional information or assistance