American Red Cross

HOSPITAL PRODUCTS AND SERVICES

INTERCEPT Fibrinogen Complex

A New Development in Transfusion Medicine

Product Guide

INTERCEPT Fibrinogen Complex

The American Red Cross now offers INTERCEPT Fibrinogen Complex, available to treat and control bleeding associated with fibrinogen deficiency.

INTERCEPT® Fibrinogen Complex (IFC) is a pathogen reduced blood component for fibrinogen supplementation with a 5-day post-thaw shelf life.

IFC contains fibrinogen, factor XIII and von Willebrand factor, which are required for clot strength and hemostasis in patients with massive hemorrhage associated with fibrinogen deficiency. IFC is not cryoprecipitated antihemophilic factor (Cryo AHF), rather it is a fibrinogen complex product.

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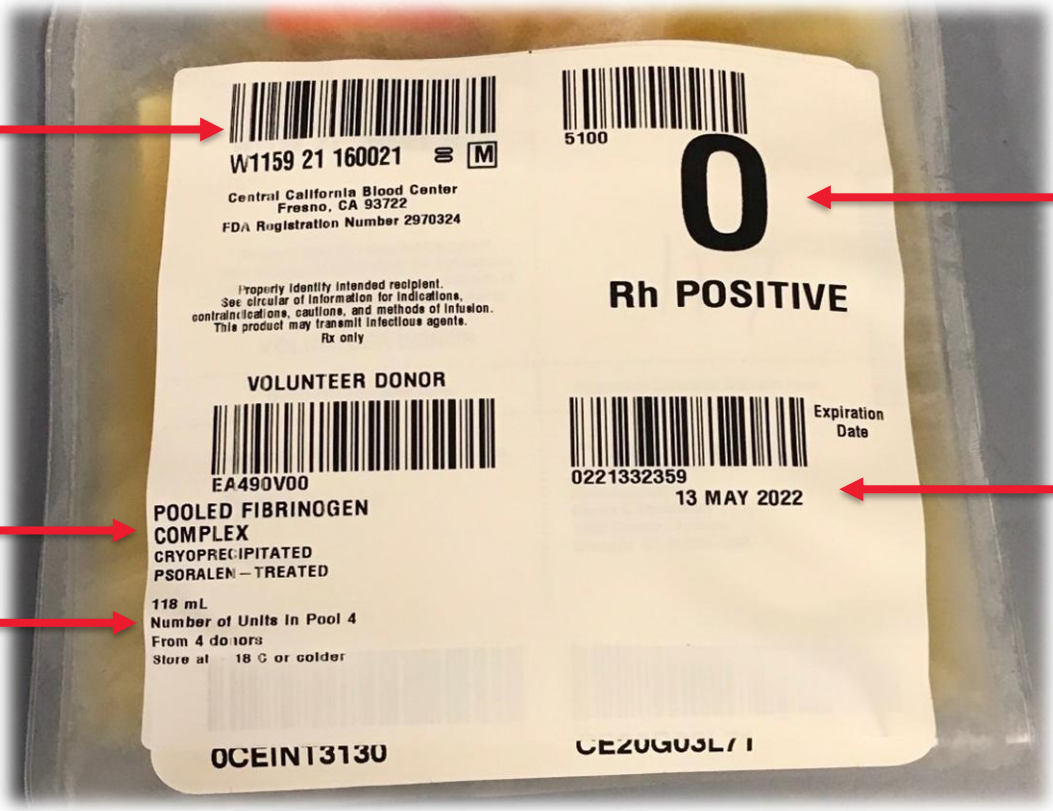
IFC Available For Order

Through its supply agreement with authorized manufacturers, the Red Cross is pleased to provide **FC15** to its hospital partners.

FC15 Product Description

- Prepared from 4 whole blood-derived plasma units
- 1,457 mg average fibrinogen content at thaw
- 120ml average volume
- 12-months frozen shelf-life
- 5-day post-thaw shelf life
- 2-3 cm pigtails
- Ports are folded and frozen flat before packaging

Sample Label



Laboratory IT System Set Up

Inventory & Dispensing

The following two technical tasks must be considered:

1. Build of product(s) in the system.
2. Adjustment of the system to identify IFC as an alternative fibrinogen supplementation option, if approved by your medical director or current transfusion policy.

While building and validating the products in your system, it may be helpful to confirm:

1. Blood Bank IT and Hospital IT can accept ISBT codes that begin with “EA”.
2. Product label printers can print the product description as the character length is longer.
    a. Re-labeled when thawed
3. Barcode readers are compatible.
4. Transfusion tags print the accurate product/attribute description.

Product Codes	
	**FC15 I EA490V00** • Pooled Fibrinogen Complex • Cryoprecipitated • Psoralen Treated
	**FC15 I EA496V00** • Thawed Pooled Fibrinogen Complex • Cryoprecipitated • Psoralen Treated

Laboratory IT System Set Up

Product Code Management

FC15 can be split and labeled as constituent parts following these product code division methodologies:

1. Utilize the hospital's current standard process for splitting Cryoprecipitated AHF.
2. If there is no standard process in place for splitting Cryoprecipitated AHF, hospitals should utilize the ***A, B, C, D, etc. method*** for the division of product codes:
    1. **EA496VA0**
    2. **EA496VB0**
    3. **EA496VC0**
    4. **EA496VD0**
3. When the hospital standard practice utilizes the ***part x of y method***, this product code division process is permitted:
    1. **EA496V00 part 1 of 4**
    2. **EA496V00 part 2 of 4**
    3. **EA496V00 part 3 of 4**
    4. **EA496V00 part 4 of 4**

Laboratory IT System Set Up

Authorized Manufacturers

The Red Cross does not currently manufacture IFC. In turn, we have entered into supply agreements with authorized manufacturers and will distribute IFC directly to our hospital customers. Red Cross customers will contract directly with Red Cross for IFC products.

- Hospitals should load all FINS associated with authorized manufacturers to maximize timely order fulfillment.

Facility	Facility Address	City	State	Zip	FIN	US License Number	FEI
Central California Blood Center	4343 West Herndon Ave	Fresno	CA	93722	W1159	315	2970324
LifeSouth Community Blood Centers	4039 Newberry Road	Gainesville	FL	32607	W3769	1647	3003707120
LifeSouth Community Blood Centers	4891 Ashford Dunwoody Rd	Atlanta	GA	30338	W3769	1647	3003707120
Community Blood Center of Appleton	4406 W Spencer Street	Appleton	WI	54914	W0533	866	2171896
Gulf Coast Regional Blood Center	1400 La Concha Lane	Houston	TX	77054	W0446	639	3002133806
The Blood Center of New Orleans	1116 Mckaskle Lane	Hammond	LA	70403	W0671	0354	2374536
OneBlood	700 Forest Point Circle	Charlotte	NC	28273	W0356	1875	3004054586
OneBlood	10100 Dr. Martin Luther King, Jr. St. N.	St. Petersburg	FL	33716	W0356	1875	1070196

IFC Ordering and Shipping

Ordering Information

- Scheduled orders only in order increments of 10 or 24 units
- Orders will be a mix of types, A, B & O
- IFC scheduled orders may be tracked in Connect
- Full orders must be cancelled in Connect with minimum 12 hours advance notice
- No Returns

Shipping Information

- Ground delivery via scheduled delivery route
- Fed Ex Next Day Direct ship (delivery by 10:30 AM)
- Product dating > 10 months at time of receipt
- Fed Ex box return label included with shipment

Post Ordering Process

- If delivered via Fed Ex, tracking numbers will be available in Connect to monitor delivery
- Customers experiencing an issue with an order or shipment, should contact Customer Service
- Customer should create a *Discard Transaction* in Connect to report any product quality issues including breakage, to receive the appropriate billing credit and support co-component product recalls.
- Customers are to contact the Red Cross Donor Client Support Center (DCSC) regarding any adverse transfusion events:
  - Call: 866-236-3276

American Red Cross

Handling Instructions

IFC Handling Recommendations for Hospitals

Introduction

The Red Cross is committed to providing customers with quality products and services as well as guidance on best practices for their use. INTERCEPT® Fibrinogen Complex (IFC) is approved specifically for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. The materials used in the storage containers for all blood products, including INTERCEPT Fibrinogen Complex, are susceptible to damage caused by friction, pinching, excessive pressure, heat exposure or other mechanical stresses. These containers must be handled with care, and the environment should be kept clean, to minimize the risk of damage and contamination.

The following recommendations provide best practices identified in the care and handling of final storage containers in the hospital environment, for distribution within the hospital, and transportation between hospitals.

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USE ENVIRONMENT

Inspection and Decontamination of Surfaces/ Workspaces/ Storage Areas:

- Areas should be free of objects that could result in punctures or abrasions.
- Conduct daily cleaning and disinfection on reusable equipment (i.e. storage containers) and work surfaces (i.e. counters and transport carts) that may be contaminated with any blood product.[1]
- Disinfect surfaces or equipment in the event of a leak or spill.

CONSIDERATIONS FOR HOSPITAL PROCESSES

General Product Handling for Frozen Bags:

- INTERCEPT Fibrinogen Complex may be stored at -18°C (-0.4°F) or colder for up to 12 months.
- Store boxed products standing upright on their side (long or short edge of box), or place flat and stacked in the freezer carton (Figure 1A). Do not pack other products on top. Products can be stored with (Figure 1B) or without (Figure 1C) the bubble wrap.
- Ensure manipulation does not cause pinching, friction or excessive pressure, especially in the area of the ports.

Figure 1: Freezer Storage

- Inspect the containers for scrapes or leaks throughout the handling.
- If a leak is detected:
  - Do not administer if there is evidence of container breakage or of thawing during frozen storage.
  - Take a picture of the damaged area and retain the bag for investigation.
  - Creates a Discard transaction in Connect for product quality notification

Thawing Process:

- Slide the unit out of the box gently (Figure 2A). Do not pull hard. If needed, remove or tear cardboard around unit to avoid damage to the bag which may be brittle when frozen (Figure 28).

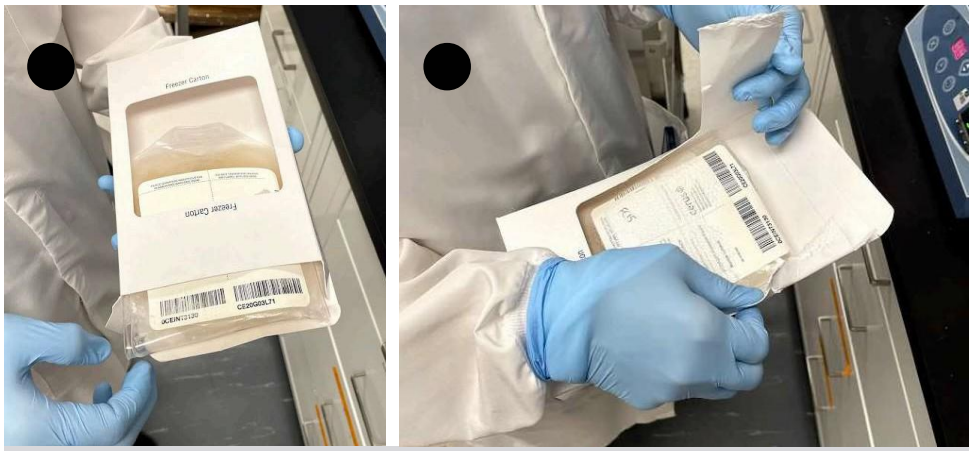

Figure 2. Removal of the Units From the Freezer Carton Prior to Thawing

- If ports and tube are folded over (Figure 3A), either allow bag to thaw briefly on a clean, disinfected flat surface to allow the ports to become flexible, or ensure that overwrap prevents ports from contact with water.
- Do not pull on the frozen ports at any time (Figure 38).
- Do not stack the bags on top of each other while thawing (Figure 3C).

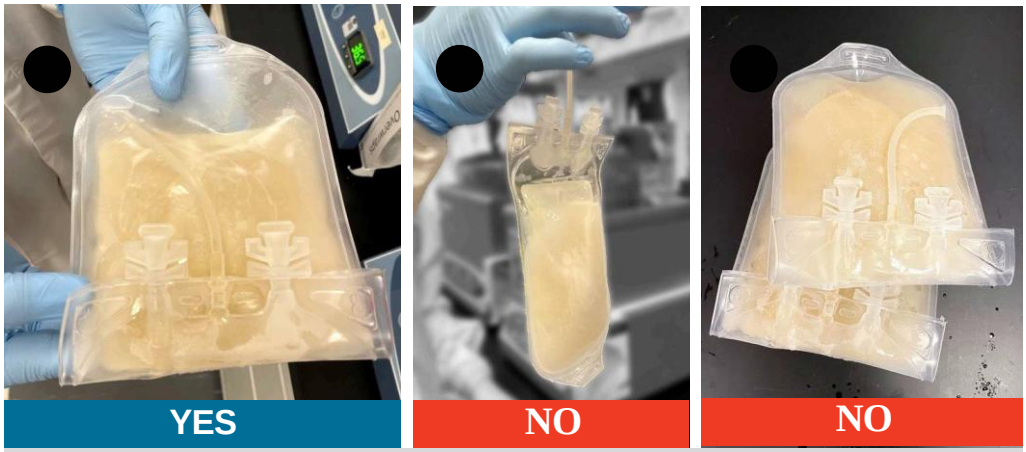

Figure 3. Handling of Frozen Ports

- The thawing process typically takes 30-45 minutes.
- Thaw according to institutional procedures.

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Thawing Process (cont'd):

- If using a water bath for thawing,
  - Place frozen unit into clean liquid-impermeable plastic overwrap with port-side up (Figure 4A-C).
    - Do not allow product to contact water.
    - Always use a new overwrap. Do not re-use overwraps.

Figure 4: Overwrap Procedure

  - Always use a clean water bath.
  - Lower unit in overwrap in the thawer, ensuring port and tubing are facing up (Figure SA).
  - Attach top of overwrap to thawer hook to prevent bag from folding over (Figure 58).
  - Ensure unfolded ports and tubing are above the water line (Figure SC).

Figure 5: Preparing the Unit for Thawing in the Water Bath

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Thawing Process (cont'd):

- Do not hold the unit by the tube (Figure 6A).
- Do not put port/tubing side down (Figure 68).
- Do not use a water bath without a new plastic overwrap (Figure 6) .

Figure 6: Incorrect Placements in Water Bath

Removal of Units from Water Bath:

- Remove unit from water bath in the overwrap with a gentle pull on the overwrap.
- Remove unit from overwrap by gently pulling on the side port or corner of the unit (Figure 7A).
- Hold the unit by the corner after removal of the overwrap (Figure 7A).
- Do not hold the unit by the ports or tubing (Figure 78).

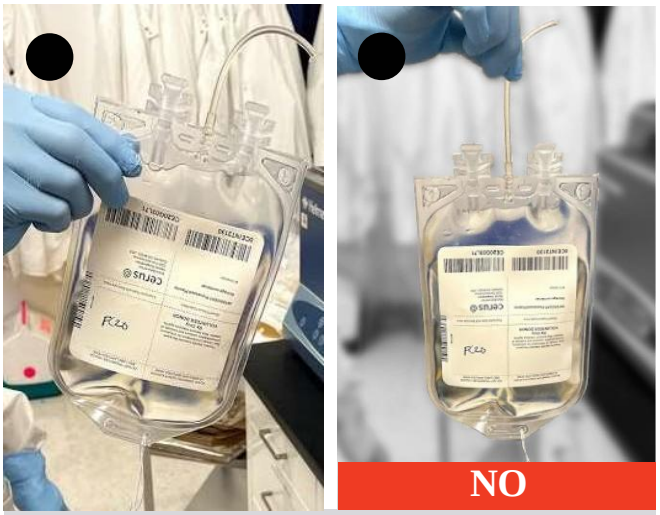

Figure 7: Handling Units

Storage of Thawed Units:

- INTERCEPT Fibrinogen Complex may be stored at room temperature in an institutionally validated room and/ or container or cabinet for up to 5 days post thaw.
- Ensure the storage area in contact with bag is clean, disinfected, and free from rough edges.
- Units may be stored in (examples of recommended practices for unit storage):
  - Institutionally validated secondary container (Figure 8A-B).
  - Within or without a paper bag with a viewing window (SC).
  - On/in a non-agitating shelf or stationary cubby (Figure 8D). If shelf or cubby is near/in equipment, ensure little to no vibration is present.

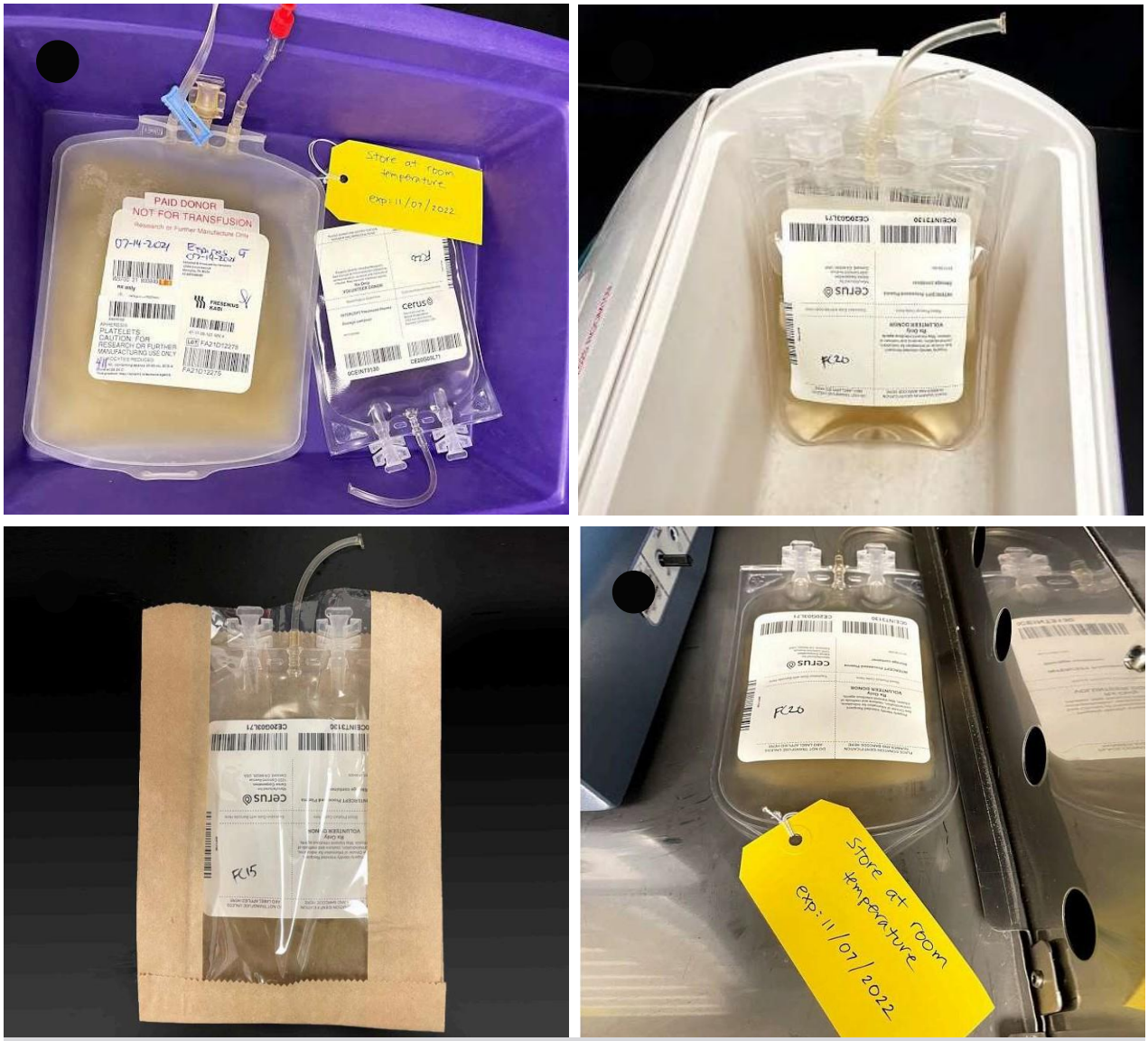

Figure 8: Room Temperature Storage Options for Thawed Units

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Storage of Thawed Units (cont'd):

- The following storage procedures should be avoided:
  - Do not store on an agitating shelf of the platelet rotator (Figure 9A).
  - Do not stack in the platelet incubator on a stationary shelf (Figure 98).
  - Do not store on rough, uneven, or sharp surfaces (Figure 9C).
  - Do not store in a wet or dirty storage container.
  - Do not store in a red blood cell refrigerator.
- At expiration, discard as medical waste according to regulations.

Figure 9: Storage Procedures to Avoid

Packing for Transport within the Hospital and from Hospital to Hospital:

- Inspect the storage containers for any scrapes or leaks. If a leak is detected follow the instructions in General Product Handling.
- Use pneumatic delivery system in accordance with AABB Guidelines.[2]
- Routinely disinfect shipping containers per institutional procedure and schedule.
- Remove any clamps from containers prior to packing.
- If using an overwrap, ensure the size is adequate for the number of containers shipped. Overwraps should be single use only.
- Pack in institutionally validated room temperature storage containers to avoid friction or pressure points.
  - Place tie tags (if any) flat against the container and near the end flap.
  - Flat placement within the shipping container is preferred with ports alternating within the stack.
  - If the container must be folded to fit within the shipping container, do not fold at the ports.
- Avoid excessive compression on contents when packing the shipping container.
- Consider acquiring shipping containers that best fit the size of the INTERCEPT Fibrinogen Complex storage container if they are unable to be placed flat.

About INTERCEPT® Fibrinogen Complex

Pathogen Reduced Cryoprecipitated Fibrinogen Complex (INTERCEPT Fibrinogen Complex) is indicated for:

- Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency.
- Control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available.
- Second-line therapy for von Willebrand disease (vWD).
- Control of uremic bleeding after other treatment modalities have failed.

Limitations of Use: Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used for replacement of factor VIII.

Contraindications

- Contraindicated for preparation of blood components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.
- Contraindicated for preparation of blood components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interactions between ultraviolet light and amotosalen.

Warnings and Precautions

- Only the INTERCEPT Blood System for Cryoprecipitation is approved for use to produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex.
- For management of patients with vWD or factor XIII deficiency, Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used if recombinant or specific virally-inactivated factor preparations are available. In emergent situations, if recombinant or specific virally-inactivated factor preparations are not available, Pathogen Reduced Cryoprecipitated Fibrinogen Complex may be administered.

Rx only. See package insert for full prescribing information.

1. AABB Technical Manual, 20th Edition (Chapter 2, Facilities, Work Environment, and Safety).
2. AABB Guide to Pneumatic Delivery Systems: Validation and Use to Transport Blood Components AABB, 2020, illus, 31 pages, ISBN 978-1-56395-410-8.


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