IMPROVACUTER® Evacuated Blood Collection System

For In Vitro Diagnostic Use

Intended Use

IMPROVACUTER® Tubes, Needles, Holders and Tourniquets are used together as a system for the collection of venous blood. IMPROVACUTER® tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory.

Product Description

IMPROVACUTER® Tubes are evacuated tubes with color-coded (see table below) Conventional Closures or Safety Caps. IMPROVACUTER® Tubes are plastic or glass tubes.
The tubes, additive concentrations, volumes of liquid additives, and their permitted tolerances, as well as the blood-to-additive ratio, are in accordance with the requirements and recommendations of CLSI H1-A5 “Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition”, the international standard ISO 6710 “Single-use containers for venous blood specimen collection” and EN standard EN14820 “Single-use containers for human venous blood specimen collection”.

Most tube types contain additives in varying concentrations dependent upon the amount of vacuum and the required additive to blood ratio for the tube. See each shelf package or case label for specific additive quantity and approximate draw volume. Additive choice depends on the analytic test method. It is specified by the manufacturer of the test reagents and/or instrument on which the test is performed.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency.

Tube Closure Color Code Recommendations			
Product Group/Items	Additive	Conventional Closure Color	Safety Cap Color
Serum Tubes			
No Additive Tube	No	Red	Red
Clot Activator Tube	Clot Activator	Red	Red
Gel & Clot Activator Tube	Gel & Clot Activator	Golden	Golden
Whole Blood/Plasma Tubes			
EDTA .K2 Tube	EDTA .K2	Lavender	Lavender
Gel & EDTA .K2 Tube	Gel & EDTA .K2	Lavender	Lavender
EDTA.K3 Tube	EDTA.K3	Lavender	Lavender
Lithium Heparin Tube	Lithium Heparin	Green	Green
Gel & Lithium Heparin Tube	Gel & Lithium Heparin	Green	Green
Sodium Heparin Tube	Sodium Heparin	Green	Green
Sodium Citrate(9:1) Tube(PT Tube or Coagulation Tube)	Sodium Citrate	Green	Green
Sodium Citrate(4:1) Tube(ESR Tube)	Sodium Citrate	Light blue	Light blue
Glucose Tube	Sodium Fluoride & Potassium Oxalate	Black	Black
Glucose Tube	Sodium Fluoride & EDTA	Gray	Gray
		Gray	Gray

IMPROVACUTER® Clot Activator Tubes

IMPROVACUTER® Clot Activator Tubes are coated with silicone and micronized silica particles to

accelerate clotting. Particles in the white or brownish film on the interior surface activate clotting when tubes are mixed 5-8 times by inversion.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

IMPROVACUTER® Gel & Clot Activator Tubes

The clot activator sprayed on the inner wall of tube can accelerate clotting. Particles in the white or brownish film on the interior surface activate clotting when tubes are mixed 5-8 times by inversion. The tube contains a gel barrier polymer at the tube bottom. The density of this material causes it to move upward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from the clot. Serum may be aspirated directly from the collection tube, eliminating the need to transfer to another container.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

IMPROVACUTER® EDTA Tubes

The interior of the tube wall is coated with either EDTA.K2 or EDTA.K3. The tube is also available with a liquid EDTA solution. The EDTA binds calcium ions thus blocking the coagulation cascade.

IMPROVACUTER® EDTA Tubes can be used in direct sampling analyzers without actually being opened. Blood smearing should be done within 3 hours after blood collection. IMPROVACUTER® EDTA Tubes are used for testing whole blood in the clinical laboratory. IMPROVACUTER® EDTA.K2 and EDTA.K3 Tubes may be used for routine immunohematology testing i.e. red cell grouping, Rh typing and antibody screens, and viral marker testing in screening laboratories.

IMPROVACUTER® EDTA.K2 and EDTA.K3 Tubes are used for testing plasma in molecular diagnostics. The performance characteristics of this device have not been established in general. Users must validate use of product for their specific molecular diagnostic assay. IMPROVACUTER® Gel & EDTA.K2 Tubes are used for testing plasma in molecular diagnostics and viral load detection.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

IMPROVACUTER® Heparin Tubes

The interior of the tube wall is coated with lithium heparin or sodium heparin to inhibit clotting. The anticoagulant heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood / plasma sample instead of clotted blood and serum.

IMPROVACUTER® Plasma Tubes with Lithium Heparin and Gel contain a barrier gel in the tube bottom. The density of this material causes it to move upward during centrifugation to the plasma-cell interface, where it forms a barrier separating plasma from cells. Plasma may be aspirated directly from the collection tube, eliminating the need for transfer to another container.

IMPROVACUTER® Heparin Tubes are used for plasma determinations of routine clinical chemistry tests. Lithium determinations should not be performed in IMPROVACUTER® Lithium Heparin tubes. Sodium determinations should not be performed in IMPROVACUTER® Sodium Heparin tubes.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

IMPROVACUTER® Sodium Citrate 9:1 Tubes (PT Tubes or Coagulation Tubes)

IMPROVACUTER® Sodium Citrate 9:1 Tubes contain buffered sodium citrate additive. Citrate Concentrations of either 0.109 mol/l (3.2 %) or 0.129 mol/l (3.8 %) are available. The choice of the Concentration depends upon the policies of the laboratories. The mixing ratio is 1 part citrate to 9 parts blood.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

IMPROVACUTER® Sodium Citrate 4:1 Tubes (ESR Tubes)

IMPROVACUTER® Sodium Citrate 4:1 Tubes are used for blood sedimentation rate testing. ESR measurements refer to the Westergren method. IMPROVACUTER® Sodium Citrate 4:1 Tubes contain buffered sodium citrate additive. Citrate concentrations of either 0.129 mol/l (3.8 %) or 0.109 mol/l (3.2 %) are available. The choice of the concentration depends upon the policies of the laboratories. The mixing ratio is 1 part citrate to 4 parts blood.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Instructions For Use (IFU)

IMPROVACUTER® Glucose Tubes

IMPROVACUTER® Glucose Tubes are available with different additives. The tubes contain a stabilizer and an anticoagulant, Sodium Fluoride and Potassium Oxalate or Sodium Fluoride and EDTA. Glucose tubes are suitable for the analysis of blood sugar and lactate.
See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

IMPROVACUTER® Tubes for Blood Banking

IMPROVACUTER® Plastic Serum Tubes, IMPROVACUTER® Plastic EDTA.K2 Tubes, IMPROVACUTER® Glass Serum Tubes, and IMPROVACUTER® Glass EDTA.K3 Tubes, may be used for routine immunohematology testing and blood donor screening for infectious disease. The performance characteristics of these tubes have not been established for immunohematology testing and infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

IMPROVACUTER® Gel & Clot Activator Plastic Tubes and IMPROVACUTER® Gel & Clot Activator Glass Tubes may be used for routine blood donor screening and diagnostic testing of serum for infectious disease. The performance characteristics of these tubes have not been established for infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

Limitations of System

The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Tubes with smaller draw volume may fill more slowly than tubes of the same size with greater draw volume.

For the tubes which should be centrifuged to obtain serum or plasma for testing, whether separator gel is present or not, standard processing conditions do not necessarily completely sediment all cells. Accordingly, cell -based metabolism, as well as natural degradation may affect serum/plasma analytical concentration or activities after centrifugation. It is recommended that testing for TBIL, DBIL and HCG be performed as soon after collection and separation as possible. Due to natural degradation, delay in separation of the serum/plasma from the cellular mass or in testing after separation will result in erroneous results for those analytes. Analyte stability should be evaluated for the storage containers and conditions of each laboratory.

The flow properties of the barrier material are temperature-related. Tubes should not be re-centrifuged once barrier has formed.

IMPROVACUTER® Gel & Clot Activator Tubes are not recommended for Therapeutic drug monitoring (TDM), blood banking and infectious disease performance. The performance characteristics of these tubes have not been established for TDM, blood banking and infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

IMPROVACUTER® Plasma Tubes with Lithium Heparin and Gel are not recommended for the collection of samples for blood banking procedures.
Do not use IMPROVACUTER® Tubes containing lithium heparin for lithium measurement.
For coagulation tests, if patient hematocrit is above 55%, the final citrate concentration in the specimen should be adjusted.

Cautions and Warnings

Cautions

1. Refer to the instrument assay's instructions for use for information on the correct sample material, correct storage and stability.
2. Do not use blood collection tubes or needles if foreign matter is present.
3. The paper label covering the connection of the needle shields will tear when the needle is opened. Do not use needle if label has been torn before venipuncture.
4. **Prevention of Backflow**
   Since some evacuated blood collection tubes contain chemical additives, it is important to avoid possible backflow from the tube during blood collection, to minimize the risk of adverse

patient reactions. To guard against backflow, observe the following precautions:

a) Place patient's arm in a downward position.

b) Hold tube with the stopper uppermost.

c) Release tourniquet as soon as blood appears in tube.

d) Make sure tube additives do not touch stopper or end of the needle during venipuncture.

5. Do not shake. Vigorous mixing may cause foaming or hemolysis.
6. If serum tubes are not mixed immediately after collection, incomplete separation of serum may occur. This may also result in delayed clotting and fibrin formation.
7. Separation of serum or plasma from cells by centrifugation should take place within 2 hours of collection to prevent erroneous test results unless conclusive evidence indicates that longer contact times do not contribute to result error.
8. Do not remove conventional rubber stoppers by rolling with thumb. Remove stoppers with a twist and pull motion. Removal by rolling with the thumb is not recommended.
9. Storage of glass tubes containing blood at or below 0ºC may result in tube breakage.
10. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
11. Overfilling or underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.

Warnings

1. Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to bloodborne pathogens.
2. Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adaptors and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector, if the blood collection device provides one. However, the policies and procedures of your facility may differ and must always be followed.
3. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
4. Transferring a sample collected using a syringe and needle to a tube is not recommended. Additional manipulation of sharps, such as hollow bore needles, increases the potential for needlestick injury.
5. Transferring samples from syringe to an evacuated tube using a non-sharps device should be performed with caution for the following reasons:
   - Depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing a potential blood exposure.
   - Using a syringe for blood transfer may also cause over or under filling of tubes, resulting in an incorrect blood-to-additive ratio and potentially incorrect analytic results.
   - Evacuated tubes are designed to draw the volume indicated. Filling is complete when vacuum no longer continues to draw, though some tubes may partially fill due to plunger resistance when filled from a syringe. The laboratory should be consulted regarding the use of these samples.
6. If blood is collected through an intravenous (I.V.) line, ensure that line has been cleared of I.V.

solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from I.V. fluid contamination.

7. Discard blood collection tubes in biohazard containers approved for their disposal.

Storage & Shipping Information

Storage

Storage tubes at 4-25℃（39-77°F）, unless there is other notice on the package or label. All liquid preservatives and anticoagulants are clear and colorless. Do not use if they are discolored or contain precipitates. Clot activator may be white or brownish; fluoride and fluoride/oxalate may be pale pink. Do not use if color has changed. EDTA or clot activator spray coated additives may have a brownish appearance; this does not affect the performance of the EDTA additive or clot activator. Do not use tubes after their expiration date. Tubes expire on the last day of the month and year indicated.

Shipping Information

Normal shipping; Normal dry container

High Altitude

For collection at high altitude (above 400m) we recommend specific tubes designed for actual local altitude according to customer requirements. The vacuum in these tubes compensates for the lower outer pressure.

Specimen Collection and Handling

Recommended Order of Draw (according to CLSI H3-A6 Standard)

The following order-of-draw is recommended when drawing multiple specimens for clinical laboratory testing during a single venipuncture. Its purpose is to avoid possible test result error due to cross contamination from tube additives (e.g., serum tubes containing a clot activator may cause interference in coagulation testing).

1) Blood Culture tube
2) Coagulation Tubes*
3) Serum Tubes with or without clot activator, with or without gel
4) Heparin Tubes with or without gel/ plasma separator
5) EDTA tubes
6) Glucose tubes
7) Others

*When drawn first then only suitable for routine tests (i.e. PT and APTT)

NOTES:

a) Gel separator tubes with clotting activators or anticoagulants are classified as additive tubes. These tubes should be drawn after the coagulation tube (blue top) and before other additive tubes (green, lavender, gray). All additive tubes should have a complete draw.

b) No additive tubes may be drawn before the coagulation tube.

c) If a winged blood collection set is used, the first tube in the series will be under-filled. Therefore, if a coagulation specimen is drawn first, a discard tube (a non-additive or coagulation tube) is

recommended to be drawn prior to this tube to fill the blood collection set tubing's "dead space" with blood. This step will ensure the proper anticoagulant-to-blood ratio. The discard tube does not need to be filled completely.

d) Even though studies have shown that PT and APTT tests are not affected if drawn first in a tube series, it is advisable to draw a second tube for other coagulation assays, since it is not known whether or not these tests will be affected.

e) When a syringe system is used and a large specimen is taken, part of the blood from the second syringe should be used for the coagulation specimen. In the case of any unexplained abnormal coagulation test result, a new specimen should be obtained and the test repeated. If heparin contamination is suspected, the test should be repeated after the specimen is treated with a method that removes or neutralizes heparin.

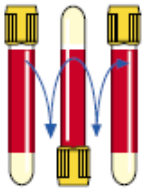
f) Always follow your facility's protocol for Order of Draw. It is the laboratory's ultimate responsibility to verify that a change from one tube to another does not significantly affect analytical results obtained from patient samples.

Specimen Collection

WEAR GLOVES DURING VENIPUNCTURE AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

■ *Using Blood Collection Set*

1. Select tube or tubes appropriate for required specimen
2. Open the primary package of blood collection set. Take blood collection set out and remove the needle shield, twist the conical fitting of the luer adapter in a clockwise direction to ensure the luer adapter firmly fitted.
3. Thread the closure-penetration end of needle into the holder. Be sure the closure-penetration needle is firmly seated to ensure this end of needle does not unthread during use.
4. Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. Use your institution's recommended procedure for standard venipuncture technique and sample collection. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEASING.
5. Perform venipuncture. A blood flashback signs a successful venipuncture
6. Push tube into holder, puncturing stopper diaphragm. Center tubes in holder and closure-penetration needle vertically penetrates the stopper diaphragm to prevent sidewall penetration and subsequent premature vacuum loss.
7. Remove tourniquet as soon as blood appears in tube. Always keep tube stopper upper-most during blood collection. Do not allow contents of tube to contact the stopper or end of the needle during procedure. Always hold in place by pressing the tube with thumb to ensure complete vacuum draw.
8. When first tube has filled to its stated volume and blood flow cease, remove it from holder.
9. Place succeeding tubes in holder, puncturing diaphragm to begin flow. See Recommended Order or Draw.
10. Immediately and gently make 5 to 8 times inversion by inverting the filled tubes. One inversion is turning the tube upside-down and returning it to its upright position.
11. As soon as blood stops flowing in the last tube, remove needle from vein, keep the



blood in the tubing flowing into the tube till filled to its stated volume, remove tube from holder, applying pressure to puncture site with dry swab until bleeding stops.

12. Dispose of needle and holder per your facility's policy

■ *Using Multi-sample Needle*

1. Select tube or tubes appropriate for required specimen
2. Assemble needle in holder. Be sure needle is firmly seated to ensure needle dose not unthread during use
3. Prepare venipuncture site with an appropriate antiseptic. Use your institution's recommended procedure for standard venipuncture technique and sample collection.
4. Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. Use your institution's recommended procedure for standard venipuncture technique and sample collection. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEASING.
5. Place patient's arm in a downward position.
6. Remove needle shield. Perform venipuncture with arm downward and tube upper-most.
7. Push tube into holder, puncturing stopper diaphragm. Center tubes in holder and closure-penetration needle vertically penetrates the stopper diaphragm to prevent sidewall penetration and subsequent premature vacuum loss.
8. Remove tourniquet as soon as blood appears in tube. Always keep tube stopper upper-most during blood collection. Do not allow contents of tube to contact the stopper or end of the needle during procedure. Always hold in place by pressing the tube with thumb to ensure complete vacuum draw.
9. When first tube has filled to its stated volume and blood flow cease, remove it from holder.
10. Place succeeding tubes in holder, puncturing diaphragm to begin flow. See Recommended Order or Draw.
11. Immediately and gently make 5 to 8 times inversion by inverting the filled tubes. One inversion is turning the tube upside-down and returning it to its upright position.
12. As soon as blood stops flowing in the last tube, remove tube from holder, remove needle from vein, applying pressure to puncture site with dry swab until bleeding stops.
13. Dispose of needle and holder per your facility's policy

Clotting Instructions

Allow blood to clot thoroughly before centrifugation. The recommended minimum clotting time for IMPROVACUTER® Gel & Clot Activator Tube is 30 minutes. Tubes with clot activator or/and gel should be inverted 5-8 times.

Minimum Clotting Time Recommendations	
Product	**Time(min)**
No Additive Tubes	60
Clot Activator Tubes	30
Gel & Clot Activator Tube	30

Notes:

1) Recommended time is based upon an intact clotting process. Patients with abnormal clotting due to disease, or those receiving anticoagulant therapy, as well as temperature of blood collection is low, require more time for complete clot formation.

2) Anyway make sure the blood specimen clot completely before centrifugal to minimize post clotting (fibrin build up) in serum. This could lead to contamination of the analyser and to erroneous results.
3) Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to CLSI guidelines.

Centrifugation

Cautions: Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 1300 RCF in fixed angle centrifuge heads. Always use appropriate carriers or inserts. Use of tubes with cracks or chips or excessive centrifugation speed may cause tube breakage, with release of sample, droplets, and an aerosol into the centrifuge bowl. Release of these potentially hazardous materials can be avoided by using specially designed sealed containers in which tubes are held during centrifugation. Centrifuge carriers and inserts should be of the size specific to the tubes used. Use of carriers too large or too small for the tube may result in breakage.

The following table gives recommended centrifuge RCF and time using a horizontal head (swinging bucket) centrifuge:

Centrifugation RCF and Time Recommendations		
Product	**RCF（g）**	**Time（min）**
No Additive Tubes	1500-2200	10
Clot Activator Tubes	1500-2200	10
Gel & Clot Activator Tubes	1800-2200	10
Plasma Tubes	1300-1800	10
Plasma Tubes with Gel	1500-1800	10
Sodium Citrate 9:1 Tubes(PT or Coagulation Tubes)	1500-2000	10

Notes:

1) RCF(Relative Centrifuge Force) is related to centrifuge speed setting (rpm) using the following equation:

$$rpm=\sqrt{\frac{RCF\times 10^5}{1.12\times r}}$$

where “r”, expressed in cm, is the radial distance from the center of the centrifuge head to the bottom of the tube

2) 15 minutes for all gel tubes in a fixed angle centrifuge.
3) Use of alternate centrifugation conditions (e.g., higher RCF and shorter spin time) may also provide acceptable performance; this should be evaluated and validated by the laboratory.
4) Citrate tubes should be centrifuged at a speed and time to consistently produce platelet-poor plasma(platelet count <10,000/uL) according to CLSI Guidelines.
5) Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in separation of the Safety Cap from the tube or extension of the tube above the carrier. Tubes extending above the carrier could catch on centrifuge head, resulting in breakage. Balance tubes to minimize the chance of glass breakage. Match tubes to tubes of the same fill level, glass tubes to glass tubes, plastics tubes with plastics tubes, tubes with Safety Cap to others with the Safety Cap, gel tubes to gel tubes, and tube size to tube size.
6) Always allow centrifuge to come to a complete stop before attempting to remove tubes.

When centrifuge head has stopped, open the lid and examine for possible broken tubes. If breakage is indicated, use mechanical device such as forceps or hemostat to remove tubes.

Caution: Do not remove broken tubes by hand. See centrifuge instruction manual for disinfection instructions.

Barrier Information

The flow properties of the barrier material are temperature-related. Flow may be impeded if chilled before or during centrifugation and high temperature could have negative effects on the physical properties of the gel. To optimize flow and prevent heating during centrifugation, set refrigerated centrifuges at temperatures between 15-25℃ (59-77℉), and the yield of serum or plasma is ideal.

Tubes should not be re-centrifuged once barrier has formed. Barriers are more stable when tubes are spun in centrifuges with horizontal (swinging bucket) heads than those with fixed angle heads.

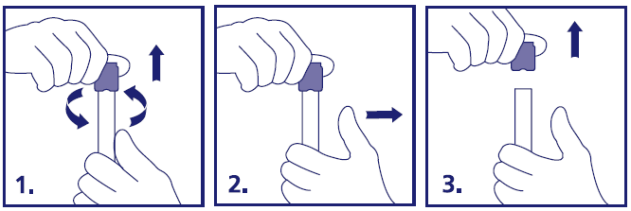
Separated serum is ready for use. The tubes may be placed directly on the instrument carrier or serum may be pipetted into an analyzer cup. Some instruments can sample directly from a separator tube with the stopper in place. Follow the instrument manufacturer's instructions.

Analytic Equivalency

Whenever changing any manufacturer's blood collection tube type, size, handling, processing or storage condition for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if changes are appropriate.

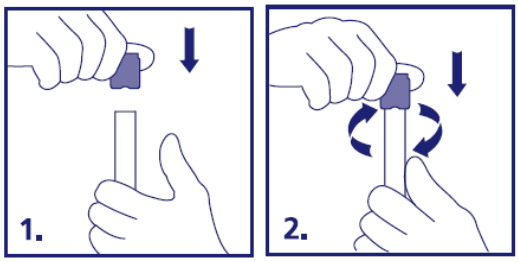
You may email: qd9@ improve-medical.com for IMPROVE MEDICAL Technical Services and information.

Instructions for Removal of Safety Cap



1. Grasp the IMPROVACUTER® Tube with one hand, placing the thumb under the safety cap. (For added stability, place arm on solid surface). With the other hand, twist the safety cap while simultaneously pushing up with the thumb of the other hand ONLY UNTIL THE TUBE STOPPER IS LOOSENED.
2. Move thumb away before lifting safety cap. DO NOT use thumb to push safety cap off tube. To help prevent injury during safety cap removal, it is important that the thumb used to push upward on the safety cap be removed from contact with the tube as soon as the safety cap is loosened.
3. Lift safety cap off tube. In the unlikely event of the plastic shield separating from the rubber stopper, DO NOT REASSEMBLE CLOSURE. Carefully remove rubber stopper from tube.

Instructions for Reinsertion of Safety Cap



1. Replace safety cap over tube.
2. Twist and push down firmly until stopper is fully reseated. Complete reinsertion of the stopper is necessary for the safety cap to remain securely on the tube during handling.

Symbol and Mark Key

Single Use	In Vitro Diagnostic Medical Device	Date of Manufacture
Expiry Date	Temperature Limitation	REF Catalog Number
LOT Batch Code	Lower Limit of Temperature	Consult Instructions for Use
STERILE Sterile	Upper Limit if Temperature	Biological Risk
This End Up	STERILE R Method of Sterilization (Irradiation)	Fragile, Handle with Care
Manufacturer	EC REP Authorized Representative	Keep Away from Sunlight
Recyclable	Caution, Consult Accompanying Documents	

References

ISO/EN Standards

ISO 6710 “Single-use containers for venous blood specimen collection”

EN 14820 “Single-use containers for human venous blood specimen collection”

ISO 11137 “Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization”

Clinical and Laboratory Standards Institute (CLSI)

H1-A5 “Evacuated Tubes and Additives for Venous Blood Specimen Collection”: Approved Standard, 5th Edition

H2-A4 “Methods for the Erythrocyte Sedimentation Rate (ESR) Test-4th Edition”; Approved Standard

H3-A6 “Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture”; Approved Standard, 6th Edition

H18-A4. “Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests”; approved guideline, 4th Edition.

H21-A5 “Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays”; approved guideline, 5th Edition

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