



Instructions for Use

AGI Disposable Inflation Device II

STERILE EO



Marketing Approval No.13B3X10277110620

Warnings

Refer to the package inserts and/or instructions for use of medical devices and pharmaceutical products used in combination with this product.

Contraindications / Prohibitions

Method of Use

1. DO NOT REUSE.
2. DO NOT RESTERILIZE.
3. This product must be used only by physicians experienced in angiography and angioplasty balloon catheter procedures. [Inappropriate manipulation may cause malfunction.]
4. Do not use agents containing organic solvents and/or oily contrast media. [Product may break.]
5. Prolonged exposure to contrast media may cause components of this product to malfunction and thereby create a safety hazard.
6. Do not exceed the maximum allowable pressure. [Malfunctions such as liquid leakage may occur.]
7. Always follow the manufacturer's directions accompanying the balloon catheter for instruction for use, maximum inflation pressure, precautions and warnings for use. The pressure displayed on the inflation device must not exceed maximum recommended balloon catheter inflation pressure.
8. Do not allow anything to come in forcible contact with the pressure gauge. [It may not display pressure correctly.]
9. Do not use any gas to inflate the balloon. [Adverse events may occur.]
10. Do not drop or allow anything to come in forcible contact with this product. [Product may break.]
11. Improper tightening of the connection between this product and Y-Adapter and accompanying equipment may result introduction of air into vascular system. Do not inject any fluid if air bubbles are visible within the fluid path of this product or the Y-Adapter.

Device Description

This product is a device intended to inflate and deflate the balloon of an angioplasty balloon catheter.

Configuration

This product consists of Pressure gauge, U-shaped plug, Syringe, Release lever, Piston, Tube, Connector, and 3-way stopcock. See Figure 1.

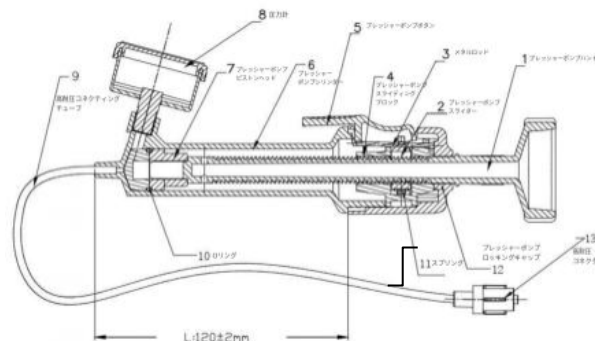


Figure 1: AGI Disposable Inflation Device II

Principle

This product is filled with a contrast medium, connected to an angioplasty balloon catheter, and used to pressurize and inflate the balloon in order to dilate the lesion.

Intended Use

This product is a dedicated hand-held inflation device with a pressure gauge used to pressurize the balloon of an angioplasty balloon catheter placed inside the patient body.

Product Specifications

- Maximum syringe volume: 20 mL
- Maximum allowable pressure: 3.0 MPa (30 atm)

Instructions for Use

1. Preparation
 - (1) Remove this product from its sterile package.
 - (2) While referring to the package inserts of the contrast medium and the angioplasty balloon catheter, prepare an inflation solution (e.g., a contrast medium diluted in physiological saline solution).
 - (3) After opening the 3-way stopcock, plunge the piston handle into the tip of the syringe while pressing the release lever.
 - (4) Place the tip of the 3-way stopcock in the inflation solution, and aspirate an appropriate quantity of the inflation solution into the syringe by slowly pulling on the piston handle while pressing the release lever.
 - (5) After closing the 3-way stopcock, with the tip of the syringe held in a downward position, pull the piston handle fully upward while pressing the release lever, and release the release lever.
 - (6) While holding the tip of the syringe in a downward position, press the release lever.

- (7) After opening the 3-way stopcock, with the tip of the syringe in an upward position, slowly turn the piston handle clockwise to purge the air completely.
- (8) After confirming the absence of air in the syringe and the tube, adjust the inflation solution contained in the syringe to the desired volume.

2. Connecting to the Angioplasty Balloon Catheter

- (1) Follow the package insert and/or instructions for use of the angioplasty balloon catheter.
- (2) Connect the angioplasty balloon catheter to the connector or the 3-way stopcock while exercising care not to let air come into the catheter.

3. Method of Operation

- (1) Method for increasing the pressure
 - 1) Turn the piston handle clockwise while checking the pressure gauge.
 - 2) Increase the pressure until the balloon is inflated as desired.
- (2) Method for decreasing the pressure
 - 1) Turn the piston handle counterclockwise while checking the pressure gauge.
 - 2) Decrease the pressure until the balloon is deflated completely.
 - 3) To depressurize the balloon rapidly, pull the piston handle while pressing the release lever.

Precautions Related to Use

1. Ensure that the needle of the pressure gauge points to 0 atm before pressurizing the balloon.
2. Ensure that no air is contained in the tube or syringe before connecting the product to the angioplasty balloon catheter.
3. Exercise care not to touch the release lever while increasing the pressure.

Precautions

1. Important Precautions
 - (1) This product is intended for use in a single patient only. Do not reuse. Because reuse may cause the risk of infection, or breakage of this product. Reuse also has the risk which cannot achieve the intended performance.
 - (2) Do not use the product for purposes other than those for which it is intended.
 - (3) Use the product immediately after opening the package.
 - (4) Do not use the product if its package is opened, damaged, or contaminated.
 - (5) Do not use the product if it is damaged or deformed.
 - (6) Do not bend the portion connecting to the tube or pull it using excessive force.
 - (7) Do not over-tighten the connector when connecting the product to the angioplasty balloon catheter.
 - (8) If any damage, such as cracks, is found in the connecting portion, replace the product with a new one immediately.
 - (9) Do not allow anything to come in forcible contact with the product.
 - (10) Do not use the product while it is entangled with other tubes or lines of concomitant medical devices.
 - (11) Pressurize and depressurize the balloon under

fluoroscopic guidance by all means.

- (12) Pressurize the balloon slowly while checking the pressure gauge. If the pressure gauge indicates anything abnormal, discontinue the pressurization.
- (13) Dispose of the used product in a safe manner exercising caution to prevent any infection.
- (14) Do not use this product after the expiration date.

2. Interactions

If any discoloration is observed, use of the contrast medium should be discontinued. (In some kinds of contrast media, copper ion elution from the connecting portion of this product may occur, resulting in a blue-green discoloration of the contrast medium.)

3. Malfunctions and Adverse Events

(1) Malfunctions

Use of this product may be associated with the following malfunctions.

<Major malfunctions>

- Malfunctioning of the pressure gauge (Pressure may not be displayed correctly, resulting in failure to pressurize the angioplasty balloon catheter appropriately.)
- Malfunctioning of the connecting portion (Leakage of the inflation solution or the inclusion of air may occur, resulting in failure to pressurize the angioplasty balloon catheter appropriately.)

(2) Adverse events

Use of this product may be associated with the following adverse events. If any of the following adverse events occurs, use of the product should be discontinued immediately and appropriate action should be taken.

- 1) Coronary artery dissection / vascular dissection
- 2) Coronary artery perforation / artery perforation, tamponade
- 3) Vascular injury
- 4) Vascular occlusion / embolization
- 5) Perforation
- 6) Hemorrhage
- 7) Hematoma
- 8) Pain / tenderness
- 9) Sepsis / infection
- 10) Allergy to agents
- 11) Thrombus formation or embolization

Storage Conditions and Expiration Date

1. Storage Conditions

- (1) Store the product at room temperature in a cool, dry, clean place away from water and direct sunlight.
- (2) Store the product in a stable condition on a level surface without inclinations, vibrations, impacts (including those during transportation), etc.
- (3) Store the product in a location away from chemical agents and gases.

2. Expiration Date

Refer to the expiration date indicated on the label of this product.

Packing

1 set / box



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<Description of Symbols>

Symbol	Definition
	METHOD OF STERILIZATION USING ETHYLENE OXIDE
	DO NOT REUSE
	DO NOT RESTERILIZE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	DO NOT USE IF PACKAGE IS DAMAGED
	LOT NUMBER
	USE BY
	MANUFACTURER
	AUTHORIZED REPRESENTATIVE