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# Occlusion Balloon System

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**Occlusion Balloon System**

70100-001 Rev. 01/06



## Instructions for Use

### International Symbols Glossary


	Attention, See instructions for use
	Use by
	Lot Number
	Do Not Reuse
	Catalogue Number
	Sterile (Ethylene Oxide)
	Date of Manufacture
	The product is placed on the market in conformity with Directive 93/42/EEC relating to medical devices
	Contents of Package

### Glosario de símbolos internacionales










	Atención. Ver las instrucciones de uso
	Fecha de caducidad
	Número de lote
	No volver a utilizar
	Número de catálogo
	Estéril (óxido de etileno)
	Fecha de fabricación
	Este producto se comercializa en conformidad con la normativa 93/42/EEC sobre dispositivos médicos
	Contenidos del paquete

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### Glossario dei simboli internazionali

	Attenzione: leggere le istruzioni per l'uso.
	Data di scadenza
	Numero di lotto
	Non riutilizzare.
	Numero di catalogo
	Sterile (ossido di etilene)
	Data di fabbricazione
	Questo prodotto è commercializzato in conformità alla direttiva 93/42/CEE relativa ai dispositivi medici.
	Contenuto della confezione

### Symboles internationaux

	Attention. Consulter le mode d'emploi
	Utiliser avant
	N° du lot
	Ne pas réutiliser
	Numéro de catalogue
	Stérile (oxyde d'éthylène)
	Date de fabrication
	Ce produit est commercialisé conformément aux dispositions de la directive 93/42/CEE relative aux dispositifs et appareils médicaux
	Contenu de l'emballage

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# Occlusion Balloon System

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## Instructions For Use

### CAUTION

- Federal (USA) Law restricts this device to sale, distribution, and use by or on the order of a physician.
- This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional radiologic procedures.
- Do not use if pouch is open or damaged.



It is important to read the instructions for use with careful attention to cautions, notes and warnings prior to using this product.



STERILE: This device is sterile and non-pyrogenic. Sterilized using ethylene oxide gas



This device is intended for **SINGLE USE ONLY. DO NOT RESTERILIZE AND/OR REUSE.**

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### CONTENTS

One (1) MTI Occlusion Balloon Catheter and one (1) MTI 0.010" Hydrophilic Guidewire.

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### DEVICE DESCRIPTION

The MTI Occlusion Balloon System is a single lumen balloon catheter that requires the insertion of the MTI 0.010" guidewire to occlude the central lumen to allow inflation of the balloon. When the distal 10 cm platinum coil tip of the guidewire is advanced to or past the catheter tip, it occludes the inflation holes allowing the balloon to inflate through catheter sideholes.

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### INDICATIONS FOR USE

The Micro Therapeutics, Inc. Occlusion Balloon Catheter is designed for the use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. The MTI Occlusion Balloon Catheter offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow.

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### CONTRAINDICATIONS

- Not intended for embolectomy and angioplasty procedures
- Not intended for use in coronary vessels
- Not intended for pediatric or neonatal use
- Not intended for use as an infusion catheter

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### WARNINGS

- Do not have a continuous flush in place while guidewire is advanced to the catheter tip in order to prevent inadvertent balloon inflation.
- Do not exceed the maximum recommended inflation volume as balloon rupture may occur.
- Verify the size of vessel under fluoroscopy, ensuring that when inflated, the balloon does not exceed size of vessel.

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### PRECAUTIONS

- Do not withdraw the guidewire to deflate the balloon, instead pull negative on the syringe to deflate.
- Do not steam shape the catheter as it may compromise the integrity of the balloon material.
- Do not use the catheter for subselective angiography as inadvertent balloon inflation could result.
- Do not advance the catheter against resistance until the source of the resistance is identified under fluoroscopy.
- Use only the recommended balloon inflation medium of 50:50 solution by volume of 60% contrast medium and normal, sterile saline.
- Do not use air or any gaseous medium to inflate the balloon.
- Avoid touching the balloon material as contrast residue can stick to gloved hands.

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**STORAGE**

This device should be stored in a dry place at between 50°F (10°C) and 90°F (32°C).

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**COMPLICATIONS**

Possible complications include, but are not limited, to the following:

- vessel rupture
- death
- stroke or infarction
- ischemia
- perforation of vessel or arterial wall
- infection
- vasospasm
- thrombus formation and release, increasing with prolonged insertion

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**COMPATIBILITY**

The maximum outer diameter of the MTI Occlusion Balloon System is 0.040", use appropriately sized guiding or angiography catheters. The Balloon System is dependent upon the 0.010" guidewire for balloon inflation.

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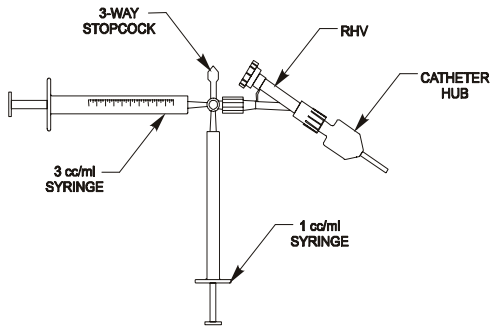
**PREPARATION OF SYSTEM**

Figure 1: Proper Set up of System

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**DIRECTIONS FOR USE**

1. Always hydrate wire first, this will allow proper hydration time (30 seconds) while prepping the balloon.
2. Attach RHV and syringes to balloon. Use Cadence syringe with 3 way stopcock and 3cc syringe.
3. Purge RHV assembly and balloon lumen with 50:50 contrast-saline solution (remove as much as air as possible).
4. Using wire introducer, advance guide wire through RHV almost to tip of balloon catheter.
5. Flush balloon lumen again to ensure air has been removed.
6. Advance guidewire past tip.
7. Inflate balloon (will stick on first inflation).
8. Check for bubbles.
9. If bubbles exist, withdraw wire inside catheter and repeat Steps 4 through 7.
10. Keep balloon tip in sterile water or saline until used with patient. This will keep wire hydrated and moving free.

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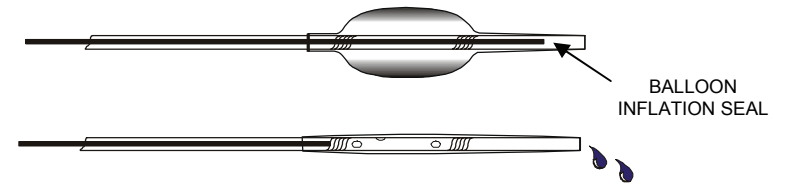


Figure 2: Guidewire Position For Balloon Inflation

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**DIRECTIONS FOR USE**

1. Advance the System through the proximal valve of the introducer sheath or the RHV attached to the hub of a guiding catheter and into the vasculature.
2. Advance a portion of the distal radiopaque marker and track to selected vessel.
3. To inflate the balloon, use the 1 cc syringe to gently infuse the desired volume of recommended contrast solution. Balloon cannot inflate unless a portion of the distal 10 cm of the guidewire tip is occluding the distal inflation holes of the catheter.

**Balloon Inflation Compliance Chart**

10 mm Balloon Length		15 mm Balloon Length		20 mm Balloon Length		30 mm Balloon Length			
Infusion Volume (cc)	Balloon Size (mm)	Infusion Volume (cc)	Balloon Size (mm)	Infusion Volume (cc)	Balloon Size (mm)	Infusion Volume (cc)	Balloon Size (mm)		
0.02	2.0	0.02	1.7	0.02	2.0	0.02	1.5		
0.04	2.6	0.04	2.4	0.04	2.5	0.04	2.0		
0.06	3.0	0.06	2.8	0.06	2.8	0.06	2.3		
0.08	3.3	0.08	3.0	0.08	3.0	0.08	2.6		
0.10	3.5	0.1	3.2	0.1	3.1	0.1	2.7		
0.12	3.7	0.12	3.4	0.12	3.2	0.12	2.8		
0.14	3.9	0.14	3.6	0.14	3.4	0.14	2.9		
0.16	4.1	0.16	3.7	0.16	3.5	0.16	3.0		
Nominal Size 4.0 mm	Nominal Size 4.0 mm	0.18	3.9	0.18	3.6	0.18	3.1		
		0.20	4.0	0.20	3.7	0.20	3.3		
		Nominal Size 4.0 mm	Nominal Size 4.0 mm	0.22	3.8	0.22	3.4		
				0.24	3.9	0.24	3.5		
				0.26	4.0	0.26	3.6		
				0.28	3.7	0.28	3.3		
		Nominal Size 4.0 mm	Nominal Size 4.0 mm	0.30	3.7	0.30	3.4		
				0.32	3.8	0.32	3.5		
				0.34	3.9	0.34	3.6		
				0.36	4.0	0.36	3.7		
				Nominal Size 4.0 mm				Nominal Size 4.0 mm	
		Maximum Rated Volume 0.16 cc		Maximum Rated Volume 0.20 cc		Maximum Rated Volume 0.26 cc		Maximum Rated Volume 0.36 cc	

4. Deflate the balloon by gently retracting the syringe plunger. Do not withdraw the guidewire from the tip of the catheter to deflate.
5. Following inflation, if flush of the central lumen is desired, withdraw the guidewire tip proximal to the proximal balloon marker, and gently flush with recommended contrast solution. Watch the balloon for potential inflation during the flush procedure.
6. Discontinue flush. Advance the guidewire beyond the catheter tip and track to the selected vessel for additional inflations.
7. After multiple inflations, the catheter and guidewire should be removed and inspected. Verify the performance of the balloon and inspect for presence of clot at the tip or inflation holes.

**TECHNICAL SUGGESTIONS**

**Guidewire Exchange Technique**

If the tip of the guidewire needs reshaping, a guidewire exchange can be accomplished using the following technique:

1. Attach a 3 cc syringe filled with the recommended contrast solution for flush to the stopcock. (As shown in Figure 1).
2. Open the stopcock to the RHV and the catheter; loosen the RHV knob. While slowly withdrawing the guidewire, gently infuse the recommended contrast solution with the 3 cc syringe while observing the balloon for potential inflation.
3. Close off the RHV knob upon complete removal of the guidewire.
4. To insert a new guidewire, open the RHV knob and insert a guidewire introducer into the hub. Advance the guidewire into the proximal shaft leaving the guidewire tip proximal to the proximal balloon marker, remove the wire introducer, and gently flush the RHV.
5. Close off the RHV knob and gently flush the catheter lumen with the 3 cc syringe prior to the guidewire passing the distal marker band.
6. Advance the guidewire tip out of the catheter tip and proceed as directed.

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**BALLOON VISUALIZATION**

- If the balloon is not visible during an inflation procedure, blood may have entered the catheter lumen. This may occur during extensive guidewire manipulation, or if the guidewire is extended beyond the catheter tip and a strong vacuum was pulled on the syringe to deflate the balloon.
- To clear the lumen of blood, deflate the balloon, withdraw the guidewire proximal to the proximal balloon marker band and perform a gentle flush procedure with the recommended contrast solution.

**BALLOON DEFLATION**

- The balloon should always be deflated with the guidewire remaining beyond the catheter tip in order to minimize aspiration of blood into the lumen.
- Do not withdraw the guidewire tip to deflate the balloon.
- Never aspirate when the guidewire is withdrawn proximal to the catheter tip.

**HYPER BALLOON DEFLATION EXPECTATIONS**

Contrast Viscosity Selection Table

Rank by Viscosity at 37°C						Contrast/Saline Dilution		
Group # (By Viscosity Range)	Brand Name	Model Description	Osmolality mOsm/kg	Viscosity @37°C	Bound Iodine Equivalent ml	50/50 Recommendation	67/33	100% Contrast
1 (1.5 to 4 CPS)	Omnipaque	140	290	1.50	140	15-30 Seconds	Deflation Time 20-35 Seconds	40-110 Seconds
	Isovue	200	413	2.00	200			
	Omnipaque	180	360	2.00	180			
	Isovue	250	524	3.00	250			
	Omnipaque	240	510	3.30	240			
	Hypaque 76	76	2160	4.00	282-292			
	Conray 60	60	1400	4.00	282			
	Renografin 76	76	1940	4.00	282-292			
	2 (4 to 9.0)	Isovue	300	616	4.70			
Ultravist		300	607	4.90	300			
Oxilan		300	585	5.10	300			
Optiray		300	651	5.50	300			
Omnipaque		300	640	6.10	300			
Visipaque		270	290	6.30	270			
Hexabrix		NA	600	7.50	320			
Oxilan		350	695	8.10	350			
Optiray		350	792	9.00	350			
3 (9 to 1.8)	Isovue	370	796	9.40	370	19-35 Seconds	Deflation Time 35-60 Seconds	135-250 Seconds
	Ultravist	370	774	10.00	370			
	Omnipaque	350	780	10.60	350			
	Visipaque	320	290	11.80	320			