stryker®
Neurovascular

TransForm®

Occlusion Balloon Catheter
(Compliant and Super Compliant)

Stryker Neurovascular (DFU Template 8in x 8in Global, 90106041AL), DFU, TransForm, EN, NV00002841-01B

TransForm®

Occlusion Balloon Catheter (Compliant and Super Compliant)

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The TransForm Occlusion Balloon Catheter consists of a single lumen catheter shaft with a balloon attached at the distal end. The balloon is available in a compliant version and a super compliant version. Radiopaque markers are located at the proximal and distal ends of the balloon to facilitate fluoroscopic visualization. The balloon catheter is recommended for use with a Stryker Neurovascular 0.014 in (0.36 mm) guidewire to seal the distal segment of the catheter lumen allowing inflation of the balloon. The guidewire can be moved distally or proximally once beyond the distal tip (seal portion) of the catheter and still maintain a positive seal for inflating the balloon. The distal outer segment of the catheter shaft is coated with a hydrophilic material that reduces friction during manipulation in the vessel. A luer fitting hub at the proximal end of the catheter is used for the attachment of accessories.

Contents

One (1) Occlusion Balloon Catheter

One (1) Compliance Chart

Table 1. Compatibility Information

Balloon Catheter Type	Balloon OD mm	Effective Length cm	Max Catheter Shaft OD F (mm)	Max Catheter Proximal Balloon Bond OD F (mm)	Min Guide Catheter ID in (mm)	Recommended Guidewire OD in (mm)
Compliant	3	150	2.8 (0.95)	3.8 (1.30)	0.053 (1.35)	Stryker Neurovascular 0.014 (0.36)
Compliant	4	150	2.8 (0.95)	3.8 (1.30)	0.053 (1.35)	Stryker Neurovascular 0.014 (0.36)
Compliant	5	150	2.8 (0.95)	3.8 (1.30)	0.053 (1.35)	Stryker Neurovascular 0.014 (0.36)
Super Compliant	3	150	2.8 (0.95)	3.8 (1.30)	0.053 (1.35)	Stryker Neurovascular 0.014 (0.36)
Super Compliant	4	150	2.8 (0.95)	3.8 (1.30)	0.053 (1.35)	Stryker Neurovascular 0.014 (0.36)
Super Compliant	7	150	2.8 (0.95)	3.8 (1.30)	0.053 (1.35)	Stryker Neurovascular 0.014 (0.36)

Precaution: The TransForm Occlusion Balloon Catheter is designed specifically for use with a Stryker Neurovascular 0.014 in (0.36 mm) guidewire. Compatibility with other guidewires has not been established.

INTENDED USE/INDICATIONS FOR USE

The Stryker Neurovascular TransForm Occlusion Balloon Catheters are indicated for use in the neuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial aneurysms.

CONTRAINDICATIONS

None known.

WARNINGS

These devices should only be used by physicians who have received appropriate training in neurointerventional surgery, interventional neuroradiology or interventional radiology.

- Use only with appropriate inflation media (of saline and contrast solution mixture). Do not use oil-based contrast agents such as Lipiodol® or Ethiodol®. Use of these contrast agents can damage the balloon.
- The compatibility of the TransForm Occlusion Balloon Catheter has not been evaluated with polyvinyl alcohol (PVA) particles or n-butyl cyanoacrylate (n-BCA).
- The balloon catheter is not intended to be used as an infusion catheter, for embolectomy or subselective angiography. The balloon may inadvertently inflate if used for these types of procedures.
- Presence of implanted devices such as clips and stents, and anatomical structures or irregularities such as bone fragments or calcifications, may damage the balloon or prevent entry/removal.
- Do not steam shape the catheter tip, as heat may damage the balloon material.
- The balloon should never be inflated or deflated with a pressure-based inflation device.
- Carefully inspect the balloon catheter prior to use. If product is damaged do not use and contact your Stryker Neurovascular representative. Use of a damaged catheter may cause serious injury.
- Verify device size, configuration and patient conditions are suitable for the specific procedure.
- Prior to introducing the balloon catheter system into the vasculature purge the system carefully to avoid accidental introduction of air into the balloon catheter system. Failure to do so may release trapped air during device use and cause neurological deficits. Do not perform initial balloon flush while in the vasculature.
- Never advance or withdraw the balloon catheter system against resistance. Movement of device against resistance could dislodge a clot, perforate a vessel wall, or damage the device. If resistance is felt when advancing or removing the balloon catheter from the guide catheter, carefully remove them as a unit to prevent damage to the blood vessel, guide catheter or the device.
- Do not inflate the balloon beyond the diameter of the vessel being treated or beyond the maximum allowed inflation volume (see tables 2-4). Excessive inflation volume may result in a ruptured balloon or damage to the vessel. Do not move the balloon catheter while the balloon is inflated.
- Withdrawing the guidewire into the balloon catheter past the distal tip (e.g., in-vivo guidewire exchange, flushing the balloon, etc.) is not recommended due to the risk of blood entry into the balloon. Blood in the balloon may result in risk of serious injury due to poor balloon visualization and the potential of flushing embolic clots. If the guidewire is withdrawn into the balloon catheter past the distal tip, withdraw the entire balloon catheter system. Prior to reintroduction, prepare the balloon catheter system per the directions in the Prepare Occlusion Balloon Catheter steps.

PRECAUTIONS

- To facilitate balloon catheter handling, the proximal portion of the balloon catheter does not have a hydrophilic surface. Greater resistance may be encountered when this section of the balloon catheter is advanced into the Rotating Hemostatic Valve (RHV).
- Exercise care in handling the balloon catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.
- To control introduction, movement, positioning and removal of the balloon catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- The TransForm® Occlusion Balloon Catheter has not been tested in coronary vessels.
- The TransForm Occlusion Balloon Catheter is not intended for angioplasty treatment of intracranial atherosclerotic disease.
- Use prior to the "Use By" date shown on the package label. Aging beyond use by date may result in material degradation resulting in adverse performance of the product.
- The TransForm Occlusion Balloon Catheter is designed specifically for use with a Stryker Neurovascular 0.014 in (0.36 mm) guidewire. Compatibility with other guidewires has not been established.
- Use caution while removing contents from packaging. Rapid removal or jerking from the package may cause catheter damage.
- Do not reinsert the balloon catheter into the dispenser coil. Reinserting the balloon catheter into the dispenser coil may cause kinking or damage to the balloon catheter. Once the balloon catheter has been hydrated, do not allow to dry.

ADVERSE EVENTS

Potential adverse events associated with the use of balloon catheters or with the endovascular procedures include, but are not limited to:

- Access site complications
- Allergic reaction
- Aneurysm perforation
- Aneurysm rupture
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

HOW SUPPLIED

Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

Do not expose the catheter to organic solvents or ionizing radiation.

OPERATIONAL INSTRUCTIONS

Preparations for Use

Warning: Carefully inspect the balloon catheter prior to use. If product is damaged do not use and contact your Stryker Neurovascular representative. Use of a damaged catheter may cause serious injury.

Warning: Verify device size, configuration and patient conditions are suitable for the specific procedure.

Precaution: Use caution while removing contents from packaging. Rapid removal or jerking from the package may cause catheter damage.

Place Guide Catheter

Prepare an appropriate guide catheter using instructions provided with the device. Establish and maintain continuous flush with appropriate flush solution through the guide catheter per standard practice (see Figure 1).

Prepare Occlusion Balloon Catheter

1. Gently remove contents from pouch using standard sterile technique.
2. Flush the balloon catheter dispenser (packaging) coil with 10 cc saline prior to removal of product to activate the hydrophilic coating of the catheter.
3. Gently remove the balloon catheter from the dispenser coil.

Precaution: Do not reinsert the balloon catheter into the dispenser coil. Reinserting the balloon catheter into the dispenser coil may cause kinking or damage to the balloon catheter. Once the balloon catheter has been hydrated, do not allow to dry.

4. Connect a RHV to the balloon catheter luer fitting. Connect a 2-way stopcock to the RHV and securely tighten. Attach a 3 cc syringe filled with a mixture of saline and contrast solution to the RHV port.
5. Using the 3 cc syringe, flush the system verifying saline-contrast mixture exits the RHV. Carefully tighten RHV and continue flushing to ensure saline-contrast mixture exits the distal tip to fully purge the system of air. Observe the balloon during flush to avoid over inflation.

Note: Partial inflation of the balloon during flushing may occur.

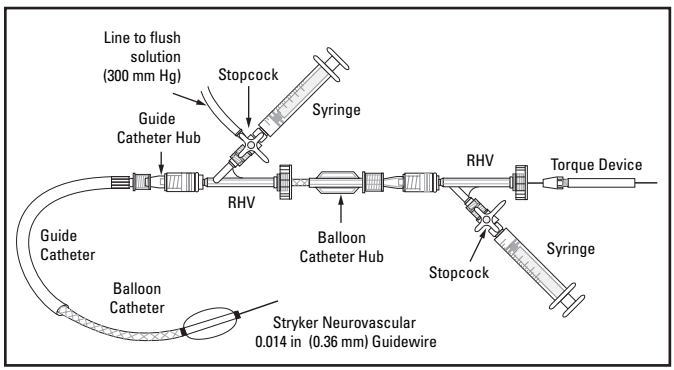

Figure 1. Example of Continuous Flush Setup

6. Carefully remove a recommended guidewire from its packaging and prepare the guidewire according to manufacturer's instructions.

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7. Loosen the RHV and advance the guidewire through the RHV and into the balloon catheter lumen so that the distal end of the guidewire is located proximal to the distal seal of the TransForm® Occlusion Balloon Catheter.

Note: Make sure the guidewire tip is within the balloon section and not through the distal end of the balloon catheter.

8. Flush the system again, verifying saline-contrast mixture exits the RHV. Carefully tighten the RHV and continue flushing to ensure saline-contrast mixture exits the distal tip of balloon catheter.

Warning: Prior to introducing the balloon catheter system into the vasculature purge the system carefully to avoid accidental introduction of air into the balloon catheter system. Failure to do so may release trapped air during device use and cause neurological deficits. Do not perform initial balloon flush while in the vasculature.

9. Slightly loosen the RHV and advance the guidewire until aligned with the distal tip of the balloon catheter to form a seal at the distal tip.

Note: When Transend® EX Platinum, Transend 300 ES or Transend 300 Floppy guidewires are used as access guidewires, advance the guidewire at least 3 cm beyond the balloon catheter tip to ensure seal integrity.

10. Using the 3 cc syringe, inflate the balloon with the saline-contrast mixture to the nominal recommended inflation volume (refer to the compliance chart) and inspect the balloon surface for any abnormalities (non-concentric shape, pin holes, etc.). While the balloon is inflated, inspect for the presence of air bubbles.
11. If air is observed in the balloon catheter system, submerge the balloon catheter tip into saline or contrast, loosen RHV slightly, pull the guidewire back from the distal tip of the balloon catheter, and with the 3 cc syringe flush to purge air bubbles. Repeat steps 9 and 10 to ensure all air is purged from the balloon catheter.
12. With the tip of the balloon catheter system submerged in saline or contrast, slightly loosen the RHV and withdraw the guidewire into the balloon to fully deflate the balloon.
13. Advance the guidewire tip to align with the balloon catheter tip. Tighten the RHV to hold the guidewire in place.
14. Replace the 3 cc syringe with a 1 cc syringe filled with saline-contrast mixture.

Note: To eliminate air bubble introduction into the RHV, fill the RHV port with saline-contrast mixture prior to connecting the 1 cc syringe.

DIRECTIONS FOR USE

1. Open the RHV on the guide catheter and introduce the balloon catheter system into the guide catheter.

Note: If Transend EX Platinum, Transend 300 ES or Transend 300 Floppy guidewires are used as access guidewires, advance the guidewire by 3 cm as soon as the balloon catheter system tip is through the RHV and inside the guide catheter. Maintain at least 3 cm wire advancement beyond the balloon catheter tip at all times.

2. Tighten the guide catheter RHV carefully around the balloon catheter system to prevent back flow, but not so tightly as to inhibit catheter movement.
3. Advance the balloon catheter system until the fluoro saver marker reaches the guide catheter RHV.
4. Under fluoroscopic guidance track the system distal to the desired treatment site.

Warning: Never advance or withdraw the balloon catheter system against resistance. Movement of device against resistance could dislodge a clot, perforate a vessel wall, or damage the device. If resistance is felt when advancing or removing the balloon catheter from the guide catheter, carefully remove them as a unit to prevent damage to the blood vessel, guide catheter or the device.

5. Position the balloon by pulling back the balloon catheter system to remove potential slack.
6. Confirm the balloon marker bands are positioned correctly relative to desired location.
7. Confirm that the guidewire is properly positioned at the distal seal to ensure balloon inflation. To inflate the balloon, use the 1 cc syringe and slowly infuse the desired volume of saline-contrast mixture (see Table 1 for nominal dimensions, and Tables 2-4 for volume/diameter information).

Warning: Do not inflate the balloon beyond the diameter of the vessel being treated or beyond the maximum allowed inflation volume (see tables 2-4). Excessive inflation volume may result in a ruptured balloon or damage to the vessel. Do not move the balloon catheter while the balloon is inflated.

Note: If the balloon is being used for an extended time such as for test occlusion, additional infusion of saline-contrast mixture into the balloon may be required to maintain intended balloon diameter.

8. Deflate the balloon by retracting the 1 cc syringe plunger. See tables 5-7 for deflation time information.

Note: It is not recommended to deflate the balloon by withdrawing the guidewire from the distal seal, as this can result in blood being pulled into the catheter lumen.

Warning: Withdrawing the guidewire into the balloon catheter past the distal tip (e.g., in-vivo guidewire exchange, flushing the balloon, etc.) is not recommended due to the risk of blood entry into the balloon. Blood in the balloon may result in risk of serious injury due to poor balloon visualization and the potential of flushing embolic clots. If the guidewire is withdrawn into the balloon catheter past the distal tip, withdraw the entire balloon catheter system. Prior to reintroduction, prepare the balloon catheter system per the directions in the Prepare Occlusion Balloon Catheter steps.

9. Fluoroscopically confirm the balloon has been deflated prior to withdrawal of the balloon catheter system.
10. If re-insertion is desired, wipe clean with sterile saline and place in a basin of the same solution.

    Repeat steps from “Prepare Occlusion Balloon Catheter” section.

Table 2. Unconstrained TransForm® Occlusion Balloon Catheter Inflation Compliance Chart (for 3 mm and 4 mm Compliant Sizes)

3 mm Diameter at Nominal				4 mm Diameter at Nominal							
10 mm Balloon Length		15 mm Balloon Length		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)	Infusion Volume (cc)	Balloon Size (mm)	Infusion Volume (cc)	Balloon Size (mm)
0.02	1.6	0.02	1.5	0.02	2.0	0.02	1.6	0.02	1.7	0.02	1.8
0.04	2.7	0.04	2.4	0.04	2.8	0.04	2.7	0.04	2.7	0.04	2.7
0.06	3.0	0.06	2.7	0.06	3.1	0.06	3.2	0.06	3.1	0.06	3.1
0.08	3.2	0.08	3.0	0.08	3.4	0.08	3.4	0.08	3.3	0.08	3.3
		0.10	3.1	0.10	3.6	0.10	3.5	0.10	3.4	0.10	3.5
		0.12	3.2	0.12	3.8	0.12	3.7	0.12	3.5	0.12	3.6
				0.14	4.0	0.14	3.8	0.14	3.6	0.14	3.7
				0.16	4.2	0.16	3.9	0.16	3.7	0.16	3.8
						0.18	3.9	0.18	3.7	0.18	3.8
						0.20	4.0	0.20	3.8	0.20	3.9
						0.22	4.1	0.22	3.9	0.22	3.9
								0.24	3.9	0.24	3.9
								0.26	4.0	0.26	4.0
								0.28	4.1	0.28	4.0
										0.30	4.0
										0.32	4.1
										0.34	4.1
										0.36	4.1
Maximum Allowed Inflation Volume 0.08 cc		Maximum Allowed Inflation Volume 0.12 cc		Maximum Allowed Inflation Volume 0.16 cc		Maximum Allowed Inflation Volume 0.22 cc		Maximum Allowed Inflation Volume 0.28 cc		Maximum Allowed Inflation Volume 0.36 cc	

Table 3. Unconstrained TransForm Occlusion Balloon Catheter Inflation Compliance Chart (for 5 mm Compliant Sizes)

5 mm Diameter at Nominal							
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	1.7	0.02	1.0	0.02	1.4	0.02	1.0
0.04	2.7	0.04	2.3	0.04	2.5	0.04	2.3
0.06	3.3	0.06	2.9	0.06	3.0	0.06	2.9
0.08	3.6	0.08	3.2	0.08	3.3	0.08	3.2
0.10	3.9	0.10	3.4	0.10	3.5	0.10	3.4
0.12	4.1	0.12	3.6	0.12	3.7	0.12	3.6
0.14	4.2	0.14	3.8	0.14	3.8	0.14	3.7
0.16	4.4	0.16	3.9	0.16	3.9	0.16	3.8
0.18	4.6	0.18	4.0	0.18	4.0	0.18	3.9
0.20	4.7	0.20	4.2	0.20	4.1	0.20	3.9
0.22	4.9	0.22	4.3	0.22	4.2	0.22	4.0
0.24	5.0	0.24	4.4	0.24	4.3	0.24	4.0
0.26	5.2	0.26	4.5	0.26	4.4	0.26	4.1
		0.28	4.7	0.28	4.5	0.28	4.1
		0.30	4.8	0.30	4.5	0.30	4.2
		0.32	4.9	0.32	4.6	0.32	4.2
		0.34	5.0	0.34	4.7	0.34	4.3
		0.36	5.1	0.36	4.8	0.36	4.3
				0.38	4.9	0.38	4.3
				0.40	5.0	0.40	4.4
				0.42	5.0	0.42	4.4
				0.44	5.1	0.44	4.5
						0.46	4.5
						0.48	4.6
						0.50	4.7
						0.52	4.7
						0.54	4.8
						0.56	4.8
						0.58	4.9
						0.60	4.9
						0.62	5.0
Maximum Allowed Inflation Volume 0.26 cc		Maximum Allowed Inflation Volume 0.36 cc		Maximum Allowed Inflation Volume 0.44 cc		Maximum Allowed Inflation Volume 0.62 cc	

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Table 4. Unconstrained TransForm® Occlusion Balloon Catheter Inflation Compliance Chart (for Super Compliant Sizes)

3 mm Diameter at Nominal		4 mm Diameter at Nominal				7 mm Diameter at Nominal					
5 mm Balloon Length		7 mm Balloon Length		10 mm Balloon Length		7 mm Balloon Length		10 mm Balloon Length		15 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)	Infusion Volume (cc)	Balloon Size (mm)	Infusion Volume (cc)	Balloon Size (mm)
0.02	1.6	0.02	1.8	0.02	1.7	0.02	1.6	0.02	1.6	0.02	1.6
0.04	2.9	0.04	2.8	0.04	2.7	0.04	2.7	0.04	2.6	0.04	2.5
0.05	3.2	0.06	3.4	0.06	3.3	0.06	3.2	0.06	3.3	0.06	3.2
0.06	3.5	0.08	3.8	0.08	3.6	0.08	3.7	0.08	3.8	0.08	3.7
		0.10	4.1	0.10	3.9	0.10	4.3	0.10	4.2	0.10	4.0
		0.12	4.4	0.12	4.2	0.12	4.7	0.12	4.5	0.12	4.3
				0.14	4.4	0.14	5.0	0.14	4.8	0.14	4.6
						0.16	5.3	0.16	5.1	0.16	4.8
						0.18	5.6	0.18	5.3	0.18	5.1
						0.20	5.8	0.20	5.5	0.20	5.3
						0.22	6.0	0.22	5.7	0.22	5.4
						0.24	6.3	0.24	5.9	0.24	5.6
						0.26	6.5	0.26	6.1	0.26	5.8
						0.28	6.7	0.28	6.2	0.28	5.9
						0.30	6.8	0.30	6.4	0.30	6.0
						0.32	7.0	0.32	6.6	0.32	6.2
						0.34	7.2	0.34	6.7	0.34	6.3
						0.36	7.3	0.36	6.8	0.36	6.4
						0.38	7.5	0.38	7.0	0.38	6.5
						0.40	7.6	0.40	7.1	0.40	6.7
								0.42	7.2	0.42	6.8
								0.44	7.3	0.44	6.9
								0.46	7.5	0.46	7.0
								0.48	7.6	0.48	7.0
										0.50	7.1
										0.52	7.2
										0.54	7.3
										0.56	7.4
										0.58	7.5
										0.60	7.5
										0.62	7.6
Maximum Allowed Inflation Volume 0.06 cc		Maximum Allowed Inflation Volume 0.12 cc		Maximum Allowed Inflation Volume 0.14 cc		Maximum Allowed Inflation Volume 0.40 cc		Maximum Allowed Inflation Volume 0.48 cc		Maximum Allowed Inflation Volume 0.62 cc	

Table 5. Average TransForm Occlusion Balloon Catheter Deflation Time (for 3 mm and 4 mm Compliant Sizes) (Seconds)

Balloon Size	Brand Name	Viscosity (cp) @ 37˚C	Contrast/Saline Dilution		
			50/50	67/33	100% Contrast
3x10	Omnipaque® 240	3.4	5	6	8
	Omnipaque 300	6.3	6	7	12
	Omnipaque 350	10.4	7	8	16
3x15	Omnipaque 240	3.4	7	8	13
	Omnipaque 300	6.3	8	10	22
	Omnipaque 350	10.4	9	11	35
4x10	Omnipaque 240	3.4	9	11	17
	Omnipaque 300	6.3	10	13	25
	Omnipaque 350	10.4	11	14	46
4x15	Omnipaque 240	3.4	11	14	23
	Omnipaque 300	6.3	14	18	37
	Omnipaque 350	10.4	16	20	63
4x20	Omnipaque 240	3.4	14	19	37
	Omnipaque 300	6.3	19	24	57
	Omnipaque 350	10.4	21	28	90
4x30	Omnipaque 240	3.4	18	23	40
	Omnipaque 300	6.3	22	27	62
	Omnipaque 350	10.4	23	33	117

Table 6. Average TransForm Occlusion Balloon Catheter Deflation Time (for 5 mm Compliant Sizes) (Seconds)

Balloon Size	Brand Name	Viscosity (cp) @ 37˚C	Contrast/Saline Dilution		
			50/50	67/33	100% Contrast
5x10	Omnipaque 240	3.4	12	16	33
	Omnipaque 300	6.3	18	22	50
	Omnipaque 350	10.4	17	23	90
5x15	Omnipaque 240	3.4	19	24	39
	Omnipaque 300	6.3	22	29	68
	Omnipaque 350	10.4	24	34	113
5x20	Omnipaque 240	3.4	20	24	60
	Omnipaque 300	6.3	27	37	91
	Omnipaque 350	10.4	31	41	122
5x30	Omnipaque 240	3.4	30	42	67
	Omnipaque 300	6.3	37	52	121
	Omnipaque 350	10.4	42	60	199

Table 7. Average TransForm® Occlusion Balloon Catheter Deflation Time (for Super Compliant Sizes) (Seconds)

Balloon Size	Brand Name	Viscosity (cp) @ 37˚C	Contrast/Saline Dilution		
			50/50	67/33	100% Contrast
3x5	Omnipaque® 240	3.4	5	5	6
	Omnipaque 300	6.3	5	6	10
	Omnipaque 350	10.4	5	6	14
4x7	Omnipaque 240	3.4	7	9	14
	Omnipaque 300	6.3	8	10	19
	Omnipaque 350	10.4	9	11	25
4x10	Omnipaque 240	3.4	7	9	14
	Omnipaque 300	6.3	8	10	23
	Omnipaque 350	10.4	10	14	43
7x7	Omnipaque 240	3.4	20	28	47
	Omnipaque 300	6.3	25	34	85
	Omnipaque 350	10.4	28	42	148
7x10	Omnipaque 240	3.4	24	32	58
	Omnipaque 300	6.3	28	40	102
	Omnipaque 350	10.4	37	51	204
7x15	Omnipaque 240	3.4	30	42	71
	Omnipaque 300	6.3	36	55	134
	Omnipaque 350	10.4	44	62	249

WARRANTY

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