SUMMARY OF SAFETY AND EFFECTIVENESS DATA

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K960070

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Device Name: NuMED Atrioseptostomy Catheter; Class II

Predicate Devices: Baxter Miller Balloon Atrioseptostomy catheter

Device Description: The NuMED Septostomy Catheter is a new balloon catheter designed for the neonate with congenital heart disease requiring septostomy. It is a dual lumen catheter, 50cm in length with a 13.5mm ± 0.5mm non-compliant balloon on the distal end. The catheter also features an end hole that will accommodate an 0.018" to 0.021" guidewire. The inflated geometry of the balloon at the rated inflation volume of 2cc is a 13.5mm ± 0.5mm sphere. There is an imaging band under the balloon for balloon positioning in the left atrium. The catheter tip is angled at 35° to facilitate passage through the interarterial opening in the left atrium. To inflate the balloon to it's maximum diameter, 2cc of diluted contrast media is pushed into the balloon extension after purging. Catheters marked every 5cm (up to 50cm) and are supplied with a one way stopcock for balloon sealing.

The non-compliant balloon and dual lumen design of the NuMED Septostomy catheter differs from other marketed catheters:

- The balloon will not deform during the procedure like a latex balloon. The result is a similar diameter opening produced using a smaller diameter balloon.
- The non-compliant balloon is heat bonded to the catheter shaft, thus reducing the risk of balloon detachment.
- The balloon design facilitates the use of a 5F introducer sheath. This will minimize blood loss in the neonates.
- The catheter end hole can be utilized for guidewire, contrast injection, or blood analysis.

Materials and colorants used in this device were approved under IDE G940143 and are the same as those used in previously approved NuMED products: PTA K931009 and PTV G890030.

Biocompatibility Testing

The materials used in the NuMED Atrioseptostomy Balloon Catheter are the same as those used in our PTA (K931009) and PTV Catheters (IDE #G890030) which have been tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing All bench testing was performed in accordance with GMP's and the results are as follows.

1. Balloon Volume vs. Diameter

Acceptance Criteria: Balloon diameter must be within ±10% of the rated diameter at the rated volume of 2cc. (i.e., 12.15mm to 14.85mm)

Justification: ±10% demonstrates the noncompliance of the balloon, and is still well below the maximum inflated diameter of 19.0mm of the predicate device .

Equipment: 3cc syringe, micrometer (CC-0078), water bath @ 98°F ±5°F, water @ 68°F ±10°F

Methodology:

Ten full length, sterile catheters with a distally mounted balloon were tested at body temperature - room temperature fluid was injected into the balloon, which was submerged in a body temperature bath. The balloons were inflated to each volume increment and measured with a micrometer (CC-0078).

Results:

Inflation Volume	Sample 1 Dia.	Sample 2 Dia.	Sample 3 Dia.	Sample 4 Dia.	Sample 5 Dia.	Sample 6 Dia.	Sample 7 Dia.	Sample 8 Dia.	Sample 9 Dia.	Sample 10 Dia.
0.5cc	7.8	7.9	7.8	8.1	8.0	8.2	8.1	8.0	8.1	7.9
1.0cc	10.0	10.2	10.1	10.7	10.5	10.8	10.6	10.7	10.6	10.5
1.5cc	11.8	11.9	11.8	12.2	12.0	12.1	12.1	12.1	12.0	12.0
2.0cc	13.0	13.2	13.1	13.7	13.5	13.6	13.9	13.8	13.6	13.5
2.5cc	13.5	13.6	13.6	13.9	13.7	13.9	13.9	13.9	13.7	13.6
3.0cc	***	***	***	***	***	***	***	***	***	***

*** Burst

Volume (cc)	Mean Diameter (mm)	Range	Standard Deviation
0.5	7.99	7.8 - 8.2	0.137
1.0	10.47	10.0 - 10.8	0.275
1.5	12.00	11.8 - 12.2	0.133
2.0	13.49	13.0 - 13.9	0.300
2.5	13.73	13.5 - 13.9	0.157

2. Bond Integrity

Acceptance Criteria: Minimum of 3 lb. at all test points

Justification: The predicate device latex balloon bond failed at a value of 2.7 lbs. in laboratory testing, using the same test methodology.

Equipment: Chatillon pull tester (CC-0013, 0-10 lbs.), circular weight, test fixture

Methodology:

Ten full length, sterile catheters with a distally mounted balloon were tested. The specified bonds were pulled at room temperature with a Chatillon pull tester.

The balloon bond testing performed simulates an actual use condition. To test the proximal balloon bond and balloon operation, the balloon was used to lift a circular weight until failure. To test the tip bond, catheters were gripped at the balloon and pulled until inner tubing failure. This tip was then gripped and the balloon was pulled until bond failure occurred.

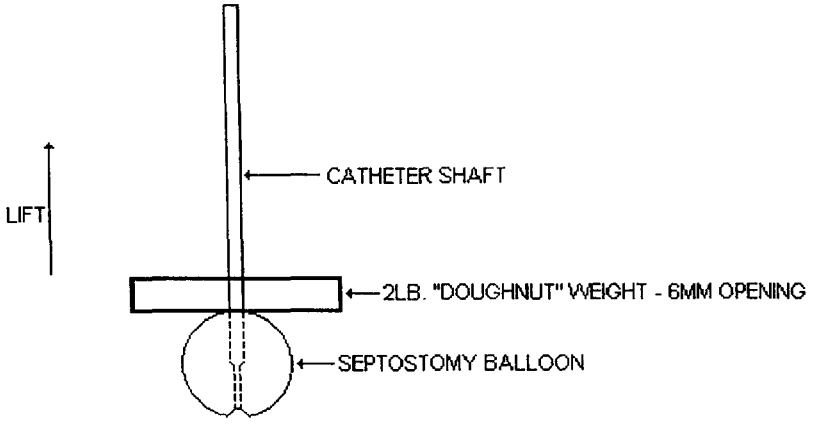
The methodology for balloon bond testing was as follows:

BALLOON BOND

[a] Inflate catheter with 2.0cc of fluid.

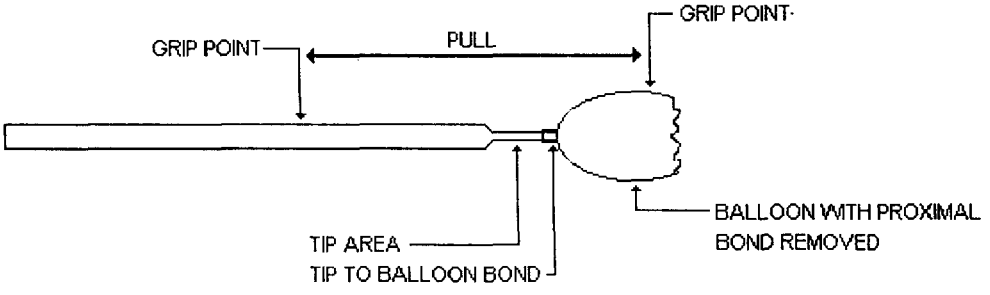
[b] Insert extensions through the weight and slide weight into place over vertically held balloon.

[c] Holding the catheter by the shaft, lift the weight off the counter (see Fig. below)



[d] Repeat this testing by adding weight rings until the balloon fails when lifting.

The additional testing was conducted on these same samples after balloon failure. The balloon was cut to reveal the balloon to catheter tip bond. The balloon was then pulled to 10 lbs. to insure that it would not come off. Since the grip points for this - test were the catheter shaft and the broken balloon this test also formulated the tip to catheter bond test. In all cases these bonds exceeded 10 lbs. (see Fig below).



Results:

Test Site	Average	Range
Distal hub to 'Y'	> 10.0 lbs.	> 10.0 lbs.
Balloon hub to extension	> 10.0 lbs.	> 10.0 lbs.
Balloon extension to 'Y' connector	> 10.0 lbs.	> 10.0 lbs.
Catheter body to 'Y' connector	> 10.0 lbs.	> 10.0 lbs.
Proximal balloon bond	8.0 lbs	7.0 - 9.0 lbs (std dev. = 1 lb.)
Tip to catheter	8.0 lbs	7.0-9.0 lbs. (std dev. = 1 lb.)
Tip to balloon	> 10.0 lbs.	> 10.0 lbs.

3. Guidewire Compatibility

Acceptance Criteria: minimal resistance while pushing catheter over guidewire. Force may not be great enough to bend guidewire.

Justification: This resistance is equal to or less than the resistance of 0.021" guidewires in balloon dilatation catheters of comparable size (i.e., same recommended guidewire size).

Equipment: Micrometer CC-0078; 0.021" guidewires

Methodology: Guidewires of a 0.021" labeled diameter were measured to ensure compliance of ± 0.001". These guidewires were then inserted through 20 full length sterile catheters. The guidewires were gripped at 2" from the guidewire hub and pushed through the catheter tip.

Results:

In no case was the guidewire kinked or was the force in excess of that necessary to insert a guidewire into a similar catheter. NuMED catheters are 100% inspected with the appropriate pin gauge for QC acceptance prior to release for packaging.

Model	n	Average	Std. Deviation	99.9% Confidence	Range
2100-01	20	NA	NA	NA	All acceptable

4. Maximum Luminal Injection Pressure

Acceptance Criteria: Must withstand 500 psi

Justification: Predicate device does not allow for pressure injection, this value is equivalent to the currently marketed Berman Angiographic catheter, of the same French size.

Equipment: pressure gauge CC-0115, 0-4000 psi, pressure generating apparatus

Methodology:

Ten sterilized, full length test catheters with balloon attached were used. The catheter tip was plugged (using a stainless steel pin) on each catheter to give a static pressure measurement. Catheters were pressurized to 750 PSI, a value in excess of that normally used in the cath lab, and then pressurized to failure. The following values are the data acquired from this testing. A limit of 600 psi will be added to the injection criteria.

Results:

Sample #	750 psi Injection	Burst Pressure
1	Pass	875 psi
2	Pass	950 psi
3	Pass	950 psi
4	Pass	900 psi
5	Pass	950 psi
6	Pass	880 psi
7	Pass	890 psi
8	Pass	890 psi
9	Pass	890 psi
10	Pass	880 psi
SUMMARY	All Samples Passed 750 psi	905.5 psi Average Burst

Mean	Range	Standard Deviation	99% Confidence
905.5 psi	875 - 950 psi	31.486	741.7 lb.

5. Multiple Inflation Testing

Acceptance Criteria: The balloon diameter must still be within ± 10% after 40 inflation/deflation cycles.

Justification: Industry standard for multiple inflations is 40 cycles.

Equipment: micrometer CC-0078, 3cc syringe, water bath @ 98°F ± 5°F, water @ 68°F ± 10°F

Methodology:

Ten full length catheters were sterilized and inflated with the recommended volume. The test was conducted at body temperature. The test sample was inflated, the O.D. measured, then deflated. All samples were inflated 50 times with no failures or leaks. One sample was inflated 500 times without failure. The diameter, at maximum volume of 2cc, was virtually unchanged from the first to the fiftieth inflation, since the non-compliant balloon was not stressed during inflation. This explains why the one sample inflated 500 times did not fail.

Results:

The raw data for the multiple inflation testing is as follows: All samples were tested 50 times with #10 tested 500 times. Individual diameter measurements were not taken on all 500 inflations of the sample. The following is the statistical analysis of balloon diameter change after 50 inflations. The raw data is enclosed within this section.

Mean: 0.15 Range: 0.1 - 0.3 Standard Deviation: 0.085

6. Injection Rate

Acceptance Criteria: Demonstrate that this device can be used for fluid injection.

Justification: The predicate device does not have a through-lumen and cannot be used for this purpose.

Equipment: NuMED hydraulic pressure injector; Pressure Gauge CC-0115, 0-4000 psi; water @ 68°F ± 10°F

Methodology:

The injection rate test was conducted on 10 full length sterilized catheters. The purged catheters were attached to the NuMED hydraulic pressure injector and the injection pressure was set at 300 psi. The injection machine consists of a hydraulic cylinder with a pressure gauge mounted at the fluid outlet. The hydraulic arm exerts a pressure on a metal syringe to expel fluid. This machine was attached directly to the distal port of the catheter and the injection pressure read 300 psi. The catheters were then subjected to a 5 second pressure injection. The injection fluid was then measured and a cc/sec value was calculated. The injection media used was room temperature water.

Results:

Sample #	Qty Fluid Injected	Calculated Rate (cc/sec)
1	21cc	4.2
2	19cc	3.8
3	21cc	4.2
4	20cc	4.0
5	19cc	3.8
6	18cc	3.6
7	20cc	4.0
8	18cc	3.6
9	22cc	4.4
10	22cc	4.4

Mean	Range	Standard Deviation	99% Confidence
4cc/sec	3.6 to 4.4	0.298	2.45 cc/sec

7. Luminal Frequency Response

These catheters are not recommended for use in measuring luminal frequency.

8. Balloon Deflatability

Acceptance Criteria: Deflatation achieved in less than 20 seconds.

Justification: As per Dr. Ziyad Hijazi, the maximum allowable deflation time was set at 20 seconds.

Equipment: 3.0cc syringe, stopwatch, silicone sheeting

Methodology:

Deflation testing was performed at NuMED in a simulated use condition in the laboratory. A total of (5) full length, sterile catheters were introduced into a section of silicone sheet, then inflated with a 30% solution of Renographin and water. They were then pulled through the sheet to simulate the septostomy procedure. These catheters were then deflated using the same 3.0cc syringe used for inflation.

Results:

Sample No.:	1	2	3	4	5
Deflation Time:	10 sec.	12 sec.	11 sec.	11 sec.	11 sec.

Mean: 11 sec Range: 10-12 sec Standard Deviation: 0.707

Balloon deflatability was also evaluated by Dr. Hijazi during animal testing performed on 2-6-95. Deflation was achieved by applying negative pressure to the balloon using a 3 cc syringe (the contrast mixture was 30%). Deflation times were 5 - 10 seconds to achieve 50% deflation and all balloons were fully deflated within 15 sec. For a faster deflation time, the physician may use a larger (10 cc) syringe. These steps have been added to the Instructions for Use.

9. Balloon Non-Compliance During Use

Acceptance Criteria: minimal deformation, as observed visually

Justification: The predicate device exhibits great deformation.

Equipment: N/A

Methodology & Results::

The catheter was used on a deer heart in the R&D lab. The balloon was slowly pulled through the septum and since this is a non-compliant material no deformation was visually observed. The Baxter Miller was then also pulled slowly through the septum of the deer heart and it was visually observed that the balloon diameter reduced in diameter. The size of the hole that was accomplished was similar in each case: 12mm hole using the 13.5mm NuMED balloon, and 11.5mm hole using the 18mm Baxter balloon.

Noncompliance of the balloon was also demonstrated and confirmed by Dr. Hijazi on the previously submitted videotape of the animal testing performed (G940143).

10. Balloon Protector Testing

Acceptance Criteria: Ability to form balloon to accept a 6F introducer

Justification: This is the label recommended introducer size for this device.

Equipment: Septostomy catheters, balloon protectors

Methodology:

The balloon protectors are made of PTFE (Teflon). It has an I.D. of 0.068" and will form and protect the balloon. Ten Atrioseptostomy catheters were fitted with balloon protectors, sent to sterilization, then opened and tested with a 6F B. Braun introducer upon return.

Results:

All catheters were admitted through the recommended 6F introducer without incident. No resistance, kinking or detrimental effects to the catheter were noted.

11. Introducer Compatibility

Acceptance Criteria: Catheter must be admitted through a 6F Introducer

Justification: This is the size of introducer recommended in the device labeling.

Equipment: 6F B. Braun Introducers, Sterile Atrioseptostomy Catheters

Methodology:

Ten catheters will be opened and tested for admittance through the recommended introducer upon return from sterilization.

Results:

All catheters were admitted through the recommended 6F introducer without incident. No resistance, kinking or detrimental effects to the catheter were noted. The catheters were then inflated and checked for any signs of damage. None were observed.

Under microscopic examination, the actual profile of the individual components is as follows: Catheter Shaft = 0.052"; Proximal Bond Area = 0.064"; Balloon Area = 0.065". All NuMED catheters are equipped with a 0.068" max. balloon protector/profiling sleeve prior to sterilization. The attachment of this sleeve ensures that the balloon will be admitted through the introducer.

B. Animal Testing

Animal testing was performed on five piglets on February 6, 1995 using finished samples of the NuMED Atrioseptostomy Catheter manufactured as per the design submitted (13.5 mm balloon, 2 cc capacity, 0.018" to 0.021" GW). The following summary was provided by Dr. Ziyad Hijazi (New England Medical Center Pediatric Cardiology) who performed the testing.

"On 2/6/95, piglet #237 weight 3.5 kg was taken to the cath lab. 5F sheath in the RFV percutaneously. A 4F wedge catheter was advanced to the LA (left atrium). An 0.018" guidewire was advanced and the septostomy catheter was exchanged for the other catheter over the wire. The balloon was inflated with 1.2 cc 30% mixture of contrast and saline, then the wire was removed and a syringe with mixture of contrast and saline was attached to this end (the distal lumen end). The balloon was pulled across the septum without difficulty. Initially 1.5 cc, then 1.8 cc, without any problem. To assess the result of pulling a fully inflated balloon (2 cc) all the way down to the IVC (inferior vena cava) resulted in perforation of the IVC. Autopsy revealed the heart size to be 35 g, the IVC revealed a laceration at the junction with the right atrium. Inspection of the septal defect size that was created revealed smooth edges, circular shape and it measures 10-12 mm in diameter.

"On 2/6/95, piglet #238 weight 3.5 kg was taken to the cath lab. 5F sheath in the RFV percutaneously. The septostomy catheter was advanced to the LA via the PFO without difficulty and without the need for a guidewire. Position was confirmed with hand injection of contrast/saline mixture in the LA. The balloon was inflated to 1.2 cc, pulling through was easy, then the catheter was re advanced to the LA without difficulty, again position was confirmed by contrast injection, balloon was inflated to 1.5 cc, this pulled through also easily, repeat procedure with a balloon capacity of 1.8 cc and 2.0 cc without any problem. Autopsy revealed heart size is 36 g. Nice size defect measuring 10-11 mm. No other findings.

"On 2-6-95, piglet #235 weight 3.2 kg was taken to the cath lab. 5F sheath in the RFV percutaneously. Septostomy using 1.2, 1.5, 1.8 and 2.0 cc successfully as described above. No problems. On occasions, the balloon could not be advanced through the defect, therefore, a guidewire was used to advance into the LA. Once in LA contrast injection demonstrated the location of the catheter tip in the LA. Autopsy revealed that the heart size is 36 g. The defect size is 11 mm. No other findings.

"On 2/6/95, piglet #239 weight 2.9 kg was taken to the cath lab. 5F sheath in the RFV percutaneously. Septostomy using 1.0, 1.5 and 1.7 cc was successful. 2.0 cc was not tried secondary to the small size of the animal. Autopsy revealed that the heart is 25 g. Good defect size 10 mm.

"On 2/6/95, piglet #236 weight 2.8 kg was taken to the cath lab. 5F sheath in the RFV percutaneously. Septostomy with 1.0, 1.5, 1.7 and 2.0 cc was uneventful. Autopsy revealed heart to be 24.5 g, defect size 11 mm.

"All procedures were recorded on videotape and slides were taken for all animals."

Dr. Hijazi provided us with copies of the slides and videotape which were included with IDE G940143 for this device.

Intended Use: This catheter is intended for balloon atrioseptostomy.

Comparison Information:

MODEL:	NuMED	BAXTER MILLER
Indications	Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.	Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.
Introducer:	6FR	8FR
Shaft Size:	5FR	5FR
Guidewire Size:	0.018" to 0.021"	N/A
Usable Length:	50cm	50cm
Balloon Capacity	2.0cc	4.0cc
Inflated Diameter:	13.5mm	19.0mm
Balloon Length:	1.35cm	NA
Max. Injection Pressure	600psi	NA
Flow Rate:	4cc per second	NA
Tip Angulation	35°	35°
Materials:	Shaft: polyamide Balloon: polyamide Image Band: Platinum	PVC Shaft Latex Balloon
Construction:	Dual lumen construction with distally mounted non-compliant balloon. Distal lumen open to tip.	PVC catheter with distally mounted latex balloon. Single Lumen with stylet for stiffness.

These catheters are marketed for balloon atrioseptostomy. The parameters of the NuMED catheters are comparable to those of the currently marketed catheters.