

## T020179-00-E HEPI Actuator 2 Assembly Oct 24 2002

### [Directory 1](#)

Pictures of the bellows leak area showing the weld assist inner band.

### [Directory 2](#)

Here are some more pics of a Hyspan bellows that has many very questionable features. Some areas look like the welding proceeded well but there are areas that appear to have needed quite a lot of filler rod. Or it could have been areas that were welded and then needed to be repaired after it leaked. It would be very hard to tell which was the case.

What can't be shown by a photograph is the waviness of the convolutions. This might not be a problem, but reflects the quality of the part.

What appears to be the resistance weld of the small weld assist band can be seen on the inside of the bellows as shown.

Note the inner weld assist band between the bellows and the large weld assist ring.

Also note the several places where the bellows does not sit flush with the surface by the weld.

### [Directory 3](#)

Here is some pics of the Ameriflex bellows that Jim Edwards sent overnight after talking to him yesterday evening at 6:30 CDT. I received it this morning at 9:00. This isn't Hyspan.

He has the print and I will contact him today.

When welding the weld assist band to the Actuator plate, the weld will pull the weld assist band and make it larger. Because of the design of the bellows to weld assist band joint, this could be putting unacceptable stress on the internal Hyspan weld. There may also be some rotation of the joint in cross section when the weld cools and pulls outward on the top of the ring. I will try to measure this today. This is our best guess at this time as for the cause of the three leaks we have had.

Another problem is that if the Hyspan bellows are that delicate and require such careful installation, how can they be trusted in service over a long period?

The Ameriflex bellows have their weld assist flange made in such a way that any welding on the flange will not stress the bellows to flange joint much. Notice the flair and how nice the weld is.

### [Soldering to Nitinol](#)

Here is an application note from Indalloy describing an allow they recommend for soft soldering our leaks. This is a possibility to attach the bellows to the plate as well.

Attached are pics of the bellows leak area showing the weld assist inner band.

10/24/2002

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[No2 Leak Area 1.jpg](#)



[No2 Leak Area 3.jpg](#)



[No2 Leak Area 4.jpg](#)

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Attached are pics of the bellows leak area showing the weld assist inner band. / No2 Leak Area 1

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No2 Leak Area 1.jpg

Attached are pics of the bellows leak area showing the weld assist inner band. / No2 Leak Area 3

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Small "original" weld assist band shown here close to the leak area.

No2 Leak Area 3.jpg

Attached are pics of the bellows leak area showing the weld assist inner band. / No2 Leak Area 4

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No2 Leak Area 4.jpg

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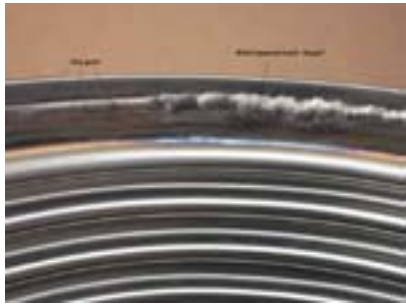
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[Suspect Weld 1.jpg](#)



[Suspect Weld 2.jpg](#)



[Suspect Weld 3.jpg](#)



[Suspect Weld 4.jpg](#)



[Suspect Weld 5.jpg](#)



[Suspect Weld 6.jpg](#)



[Suspect Weld 7.jpg](#)



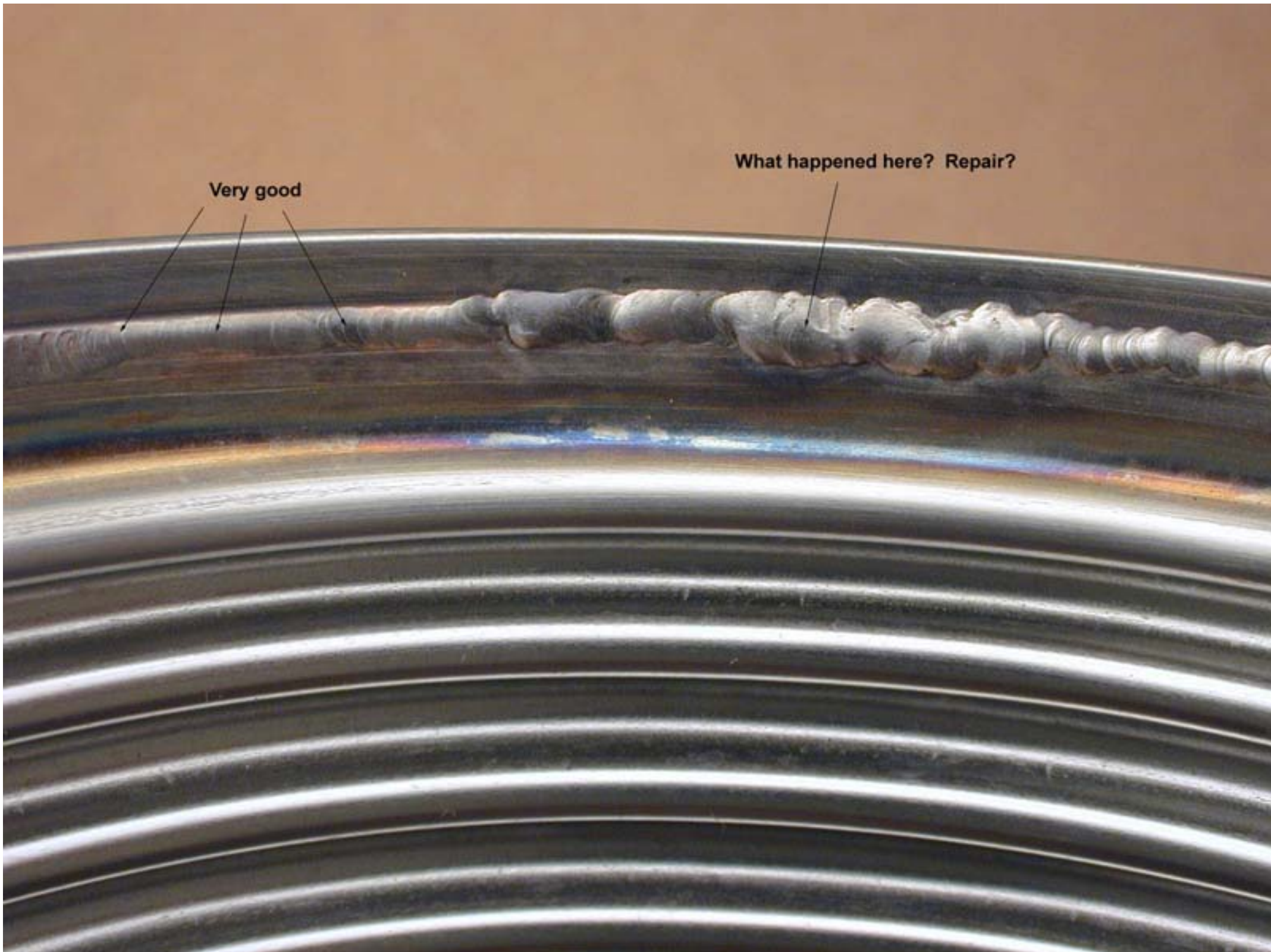
[Suspect Weld 8.jpg](#)

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Suspect Weld 4.jpg

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Suspect Weld 5.jpg

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[Ameriflex Bellows 2.jpg](#)



[Ameriflex Bellows 4.jpg](#)

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Ameriflex Bellows 1.jpg



Here is some pics of the Ameriflex bellows / Ameriflex Bellows 2

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Ameriflex Bellows 2.jpg

Here is some pics of the Ameriflex bellows / Ameriflex Bellows 4

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**Here is where the flange attaches to the bellows.**

Ameriflex Bellows 4.jpg

## SOLDERING TO NITINOL

**Nitinol (nickel/titanium alloy)** has increasingly become a very popular material in the medical industry, largely due to its shape memory characteristics, where it is often used in stents, catheters and other implants. Medical device manufacturers often wish to mechanically bond Nitinol to another metallic material, such as stainless steel, using a solder alloy.

The key to soldering to Nitinol is using an appropriate flux that will effectively reduce both the nickel and titanium surface oxides. Since the devices are used in the human body, it is important that the selected solder alloy has minimum biological activity and the flux residue is completely removed after the soldering operation. Therefore, it is imperative that the selected solder alloy contains no high toxicity metals such as lead, antimony or cadmium.

The tin-silver eutectic solder, 96.5% tin, 3.5% silver (Indalloy #121), is a preferred alloy in that the tensile strength of this solder is high, has a reasonable melting temperature of 221°C, is lead-free, and wets well to Nitinol. The gold-tin eutectic solder, 80% gold, 20% tin,

(Indalloy #182), has even higher tensile strength along with a good resistance to peel and with a melting temperature of 280°C can withstand autoclaving temperatures. In using this alloy a nitrogen protective cover gas gave more consistent results and simplified flux removal. The high gold content is also very acceptable for in vivo applications. Although these solder alloys have lower toxicity than common tin-lead solder, it is imperative that the medical manufacturer conduct the necessary tests to insure that the constituents will have no adverse health effects when used in a particular application within the human body.

In wettability tests, it was found that Indalloy Flux #2 provides the best wettability to Nitinol. Soldering temperature should be 25° to 50°C. above the liquidus temperature of the solder. Adequate post soldering cleaning of the flux residue using detergent, water and mechanical scrubbing should be performed to insure that all traces of the flux are removed. Appropriate testing should be done to insure that all traces of the flux have been removed.



All statements, technical information and recommendations contained herein are based on tests, or other information, available to us which we believe to be reliable, but the accuracy or completeness thereof is not guaranteed, and the following is made in lieu of all warranties express or implied, including warranties of merchantability and fitness. Our only obligation shall be to replace such quantities of the product as is proved to be defective provided that a claim is submitted to us within 60 days from the date of shipment. We shall not be liable for any injury, loss or damage, direct or consequential, arising out of the use of or the inability to use the product. It shall be solely the purchaser's obligation to determine the suitability of the product for his intended use and the

purchaser assumes all risk and liability whatsoever in connection therewith.

No statement or recommendation not contained herein shall have any force or effect unless in an agreement signed by an authorized representative or seller.

Since we have no means of controlling the final use of the product by the consumer or purchaser it is the responsibility of the immediate purchaser and any intermediate seller or sellers to inform the user of the purposes for which the product may be fit and suitable and of the properties of the product, including any precautionary measures which must be taken in order to insure the safety of the user and of other third persons and property.

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**INDALLOY SPECIALTY ALLOYS**

Indalloy Number	TEMP		Solidus	Elemental Composition (% by Mass)	
	Liquidus				
	°C		°C		
121	221	E	221	96.5 Sn	3.5 Ag

**MECHANICAL PROPERTIES**

Liquidus	TEMP		Density		Electrical Conductivity	Thermal Conductivity	Thermal Expansion	Tensile Strength	Shear Strength	Young's Modulus	Elongation	Brinell Hardness	Latent Heat of Fusion	Specific Heat SOLID	Specific Heat LIQUID	Indalloy Number
	°F	°F	lb/in <sup>3</sup>	gm/cm <sup>3</sup>	1.72μohms-cm	@ 85°C	@ 20°C	PSI	PSI	PSI x 10 <sup>6</sup>	%		J/g	J/g-°C	J/g-°C	
430	430		0.2659	7.36	16	.33	30	5620			73	40				121

Lead free high temp solder. Excellent thermal fatigue properties. Not recommended for soldering to gold thicker than 0.5 microns.

**NOTES**

note 1: Brinell Hardness, 2mm ball, 4kg load

note 2: Modified Brinell hardness, using 100-kg load, 1/2 min.

note 3: Depends on specimen preparation.

note 4: % elongation on 5.65 (sq. root Area) gauge length

**Conversions:**

Resistivity of IACS / Elec. conductivity %IACS = Resistivity of alloy

ex: 1.72 x 100 / %IACS = micro ohm - cm