

Bien-Air Surgery  
Rue de l'Ouest 2b  
CH-2340 Le Noirmont  
Switzerland

Bienne, March 02, 2022

To whom it may concern

**Use of cleaning adaptors for active automated cleaning with Bien-Air Surgery devices.**

*Text in French on page 2 ; Translation in French from Page 13  
Text in German on page 3 ; Translation in German from Page 21*

Bien-Air Surgery SA, as a manufacturer of medical devices, is complying with ISO 17664 and delivers validated methods for the reprocessing of re-usable devices, including cleaning and sterilization. Reprocessing indications are typically included in the dedicated instruction for use. Currently, those validated processes include both manual and automated cleaning methods.

The use of cleaning adaptors for active flushing is newly required in some fields and/or hospitals to align with new standard practices in the reprocessing field of medical devices. Bien-Air Surgery has mandated a supplier to develop custom-made cleaning adaptors for the following product families:

- PMAM and PMRM handpieces
- PM2 handpieces (including HD nose)
- Cranio-Guards
- OSSEOSTAP nose
- S120 handpiece
- Shaver blades

A complete analysis has been made by Bien-Air Surgery SA and its development partner to guarantee the safe and the efficiency use of these custom-made cleaning adaptors. Therefore, Bien-Air Surgery authorizes the use of the cleaning adaptors listed in the Appendix for active automated cleaning. Please note that the adaptors must be used together with any connecting system that includes a filter. All adaptors have to be ordered directly from their legal manufacturer (3-Mach GmbH<sup>1</sup>) who is fully responsible for these cleaning adaptors. The instruction for use will be updated to indicate this alternative.

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<sup>1</sup> Information on where to order the adaptors is available in the appendix.

## APPENDIX

All adaptors have to be ordered directly from their legal manufacturer:

3mach GmbH  
Daimlerstraße 25  
72414 Rangendingen  
Tel: + 49 (0) 74 71-98 41 18  
Fax: + 49 (0) 74 71-98 41 19

E-Mail: [info@3mach.de](mailto:info@3mach.de)  
Internet: [www.3mach.de](http://www.3mach.de)

Their online platform can be used: <https://www.medinfodesk.de/>


Your contact in Switzerland:

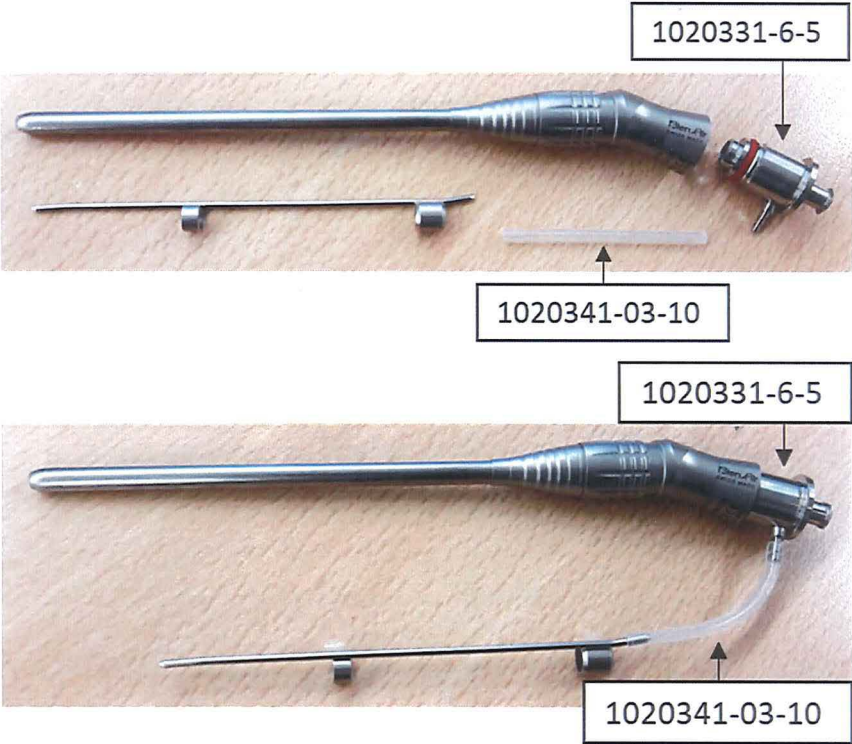
**zumstein**medizintechnik

Hühnehubelstrasse 62  
CH - 3123 Belp


[www.zumstein-online.ch](http://www.zumstein-online.ch)  
[mail@zumstein-online.ch](mailto:mail@zumstein-online.ch)  
Tel.: 031 991 47 37  
Fax: 031 991 34 77

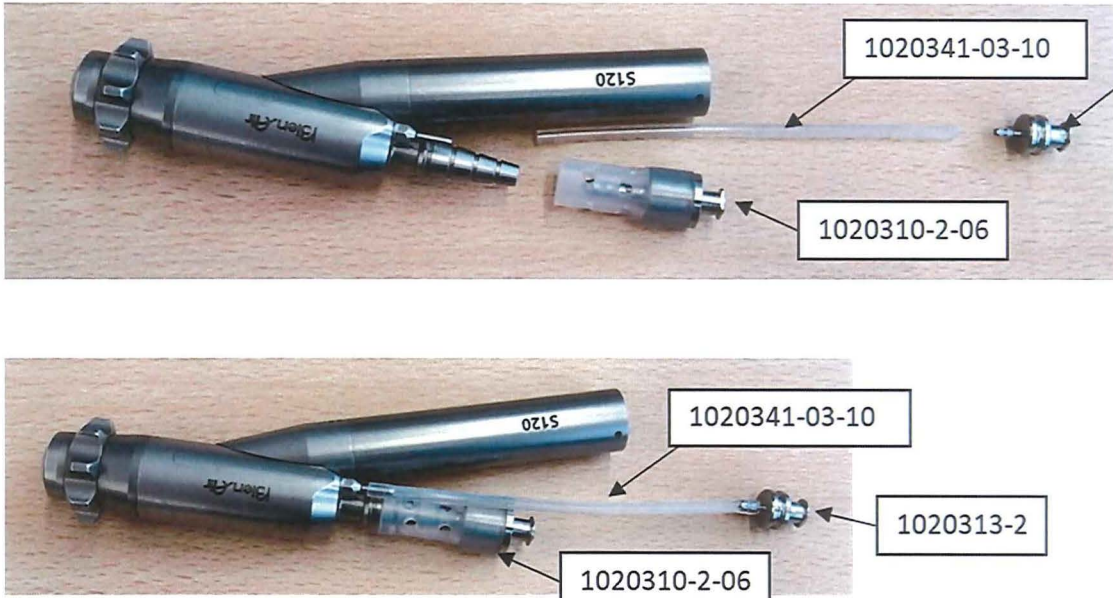
[www.zumstein-online.ch/3mach/zubehoer-bien-air-surgery](http://www.zumstein-online.ch/3mach/zubehoer-bien-air-surgery)

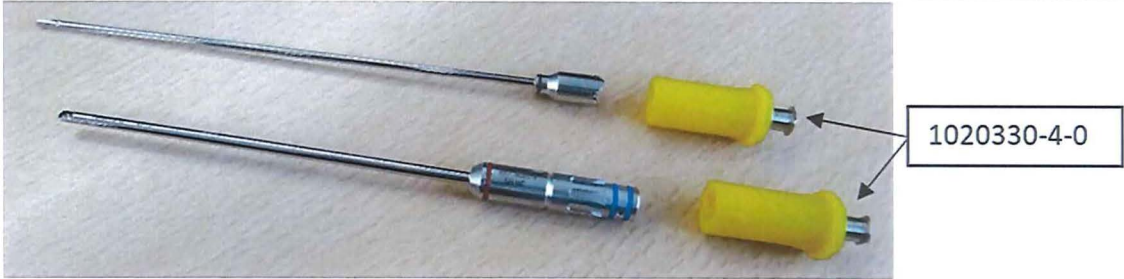

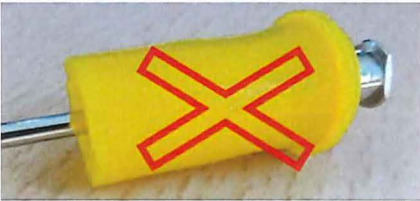
Bien-Air Surgery's products	Required component from 3-Mach	Picture of the assembly Cleaning Adaptor – Medical Device
<p><b>PMAM and PMRM handpieces:</b>                      1600207                      1600336                      1600337                      1600206                      1600295                      1600612</p>	<p>1020331-6-2                      (LLW multi-adaptor with lateral tube adaptor)</p> <p>1020341-03-10 (Tube diameter 1 mm (internal diameter), L 15 cm, set of 10)</p> <p>1020500-1-10                      (Ring, red, set of 10)</p>	 <p>Remove the irrigation tube from the handpiece nose. Then, insert the adaptor 1020331-6-2 until the two gaskets are inside the handpiece. Then connect silicone tube 1020341-03-10 on adaptor 1020331-6-2, and on the handpiece irrigation tube.</p> <p>Note: 1020500-1-10 is a set of 10 gaskets used to replace damaged gaskets from the cleaning adaptor 1020331-6-2.</p>

<p><b>PM2 handpieces</b> <b>(slim):</b> 1600765 1600766 1600767 1600768 1600769 1600977 1600978</p>	<p>1020331-6-5 (LLW multi-top adaptor with lateral tube adaptor, diameter 2.1 mm and 1 x gasket ring)</p> <p>1020341-03-10 (Tube diameter 1 mm (internal diameter), L 15 cm, set of 10)</p> <p>1020500-1-10 (Ring, red, set of 10)</p>	 <p>Remove the irrigation tube from the handpiece nose. Then, insert the adaptor 1020331-6-5 into the handpiece until the gasket is blocked inside the handpiece. Then connect the silicone tube 1020341-03-10 on the adaptor 1020331-6-5, and on the handpiece irrigation tube. Note: 1020500-1-10 is a set of 10 gaskets used to replace damaged gaskets from the cleaning adaptor 1020331-6-5.</p>
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<p><b>PM2 handpieces including HD nose:</b> 1600830 1600831 1502506</p> <p><b>Cranio-Guards:</b> 1600879 1600880 1600887 1600912 1600913</p>	<p>1020331-6-5 (LLW multi-top adaptor with lateral tube adaptor, diameter 2.1 mm and 1 x gasket ring)</p> <p>1020341-03-10 (Tube diameter 1 mm (internal diameter), L 15 cm, set of 10)</p> <p>1020331-6-3 (LLW multi-adaptor with guide pin)</p> <p>1020500-1-10 (Ring, red, set of 10)</p>	 <p>1020331-6-5</p> <p>1020341-03-10</p> <p>Insert the adaptor 1020331-6-5 until the gasket is blocked inside the handpiece. Then connect the silicone tube 1020341-03-10 on adaptor 1020331-6-5, and on the handpiece irrigation tube.</p>  <p>1020331-6-3</p> <p>Insert the adaptor 1020331-6-3 until the first gasket only is inside the HD nose or cranio-Guard. One gasket must remain outside.</p>  <p>1020331-6-3</p> <p>Note: 1020500-1-10 is a set of 10 gaskets used to replace damaged gaskets from the cleaning adaptor 1020331-6-3.</p>
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<p><b>OSSEOSTAP nose:</b> 1600685</p>	<p>1020331-6-6 (LLW multi-top adaptor with sleeve, grey)</p> <p>1020336-6 (Silicone sleeve, grey, 25 (L))</p>	   <p>Insert the adaptor 1020331-6-6 until its border gets align with the limit of the osseostap screw filet (see pictures).</p> <p>Note: 1020336-6 are replacement silicone sleeve for adaptors 1020331-6-6</p>	<p>1020331-6-6</p> <p>✓ Correct</p> <p>✗ Incorrect</p>
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<p><b>S120 handpiece:</b> 1600614</p>	<p>1020310-2-06 (LL, female, with silicone part, perforated)</p> <p>1020313-2 (LLW tube attachment)</p> <p>1020341-03-10 (Tube diameter 1 mm (internal diameter), L 15 cm, set of 10)</p>	 <p>Insert the silicone tube 1020341-03-10 on one side onto S120 irrigation tube, and on the other side on the adaptor 1020313-2 (See pictures). Insert the adaptor 1020310-2-06 on the S120 sucking tube (See pictures).</p>
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<p><b>Shaver blades:</b> 1600579 1600580 1600581</p>	<p>1020330-4-0 (LLW sleeve adaptor with sleeve, yellow)</p>	 <p>Insert internal and external tubes inside an adaptor 1020330-4-0. For internal tubes, the end of the conical part of the blades' body must be aligned with the yellow adaptor border (see pictures). External tubes must be pushed as far as possible, until it gets blocked against the bottom of the adaptor 1020330-4-0.</p>  <p>✓ Correct</p>  <p>✗ Incorrect</p> <p>Note: Two adaptors 1020330-4-0 are always needed for one device (one for the internal tube, and another for the external tube)</p>
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