

## Attachment 1 – Affected Product List (AU)

### URGENT MEDICAL DEVICE RECALL

**Bivona® Aire-Cuf®, TTS™, Uncuffed, Mid-Range Neonatal/Pediatric Tracheostomy Tube(s) and Bivona Aire-Cuf®, TTS™, Cuffless FlexTend™, TTS™ FlexTend™ Adult Tracheostomy Tube(s)**  
**ARTG:397290**

31 May 2024

| Product Item Number | Product Description                                  | Range Minimum - From Lot Number | Range Maximum - To Lot Number |
|---------------------|------------------------------------------------------|---------------------------------|-------------------------------|
| 670170              | TTS TRACHEOSTOMY TUBE 7.0MM TIGHT TO SHAFT CUFF      | 3774400                         | 4393380                       |
| 670180              | TTS TRACHEOSTOMY TUBE 8.0MM TIGHT TO SHAFT CUFF      | 3782494                         | 4396613                       |
| 750160              | AIRE-CUF TRACHY TUBE 6.0MM MID-RANGE                 | 3790021                         | 4401458                       |
| 750170              | AIRE-CUF TRACHY TUBE 7.0MM MID-RANGE                 | 3790106                         | 4393384                       |
| 750180              | AIRE-CUF TRACHY TUBE 8.0MM MID-RANGE                 | 3710823                         | 4401163                       |
| 60N025              | NEONATAL TRACHEOSTOMY TUBE                           | 3853476                         | 4400691                       |
| 60N030              | NEONATAL TRACH TUBE 3.0MM                            | 3853477                         | 4389921                       |
| 60N035              | NEONATAL TRACH TUBE 3.5MM                            | 3880712                         | 4389922                       |
| 60N040              | NEONATAL TRACH TUBE 4.0MM                            | 3868302                         | 4362872                       |
| 60NFP25             | NEONATAL TRACHEOSTOMY TUBE 2.5FLEXTEND PLUS          | 3939632                         | 4348458                       |
| 60NFP30             | NEONATAL TRACHEOSTOMY TUBE 3.0FLEXTEND PLUS          | 3868231                         | 4399162                       |
| 60NFP35             | NEONATAL TRACHEOSTOMY TUBE 3.5FLEXTEND PLUS          | 3840087                         | 4389891                       |
| 60NFP40             | NEONATAL TRACHEOSTOMY TUBE 4.0FLEXTEND PLUS          | 3840062                         | 4399164                       |
| 60NFPS35            | 3.5MM FLEXTEND NEO STRAIGHT TRACH TUBE               | 3853442                         | 4400664                       |
| 60P025              | PAED. TRACHEOSTOMY TUBE 2.5MM UNCUFFED               | 3880717                         | 4389923                       |
| 60P030              | PAED. TRACHEOSTOMY TUBE 3.0MM UNCUFFED               | 3853478                         | 4399210                       |
| 60P035              | PAED. TRACHEOSTOMY TUBE 3.5MM UNCUFFED               | 3840043                         | 4395802                       |
| 60P040              | PAED. TRACHEOSTOMY TUBE 4.0MM UNCUFFED               | 3840052                         | 4393425                       |
| 60P045              | PAED. TRACHEOSTOMY TUBE 4.5MM UNCUFFED               | 3858169                         | 4389927                       |
| 60P050              | PAED. TRACHEOSTOMY TUBE 5.0MM UNCUFFED               | 3853484                         | 4400700                       |
| 60P055              | PAED. TRACHEOSTOMY TUBE 5.5MM UNCUFFED               | 3853487                         | 4399219                       |
| 60PFP40             | PAED. TRACHEOSTOMY TUBE 4.0MM FLEXTEND PLUS          | 3868314                         | 4399170                       |
| 60PFP45             | PAED. TRACHEOSTOMY TUBE 4.5MM FLEXTEND PLUS          | 3802254                         | 4388163                       |
| 60PFP55             | PAED. TRACHEOSTOMY TUBE 5.5MM FLEXTEND PLUS          | 3868227                         | 4399172                       |
| 60PFP60             | PAED. TRACHEOSTOMY TUBE 6.0MM FLEXTEND PLUS          | 3853449                         | 4399173                       |
| 60PFPS40            | 4.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE    | 3853451                         | 4399175                       |
| 60PFPS50            | 5.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE    | 3853453                         | 4399177                       |
| 60PFPS60            | 6.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE    | 3874296                         | 4400667                       |
| 60PFS25             | PAED. TRACHEOSTOMY TUBE 2.5MM STANDARD FLEXTEND PLUS | 3868288                         | 4348474                       |
| 60PFS30             | PAED. TRACHEOSTOMY TUBE 3.0MM STANDARD FLEXTEND PLUS | 3853454                         | 4400668                       |

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|-----------------|-------------------------------------------------------------|---------|---------|
| <b>60PFS35</b>  | PAED. TRACHEOSTOMY TUBE 3.5MM STANDARD FLEXTEND PLUS        | 3840084 | 4393410 |
| <b>60PFS40</b>  | PAED. TRACHEOSTOMY TUBE 4.0MM STANDARD FLEXTEND PLUS        | 3835740 | 4399188 |
| <b>60PFS45</b>  | PAED. TRACHEOSTOMY TUBE 4.5MM STANDARD FLEXTEND PLUS        | 3843109 | 4395789 |
| <b>60PFS50</b>  | PAED. TRACHEOSTOMY TUBE 5.0MM STANDARD FLEXTEND PLUS        | 3840085 | 4399191 |
| <b>60PFS55</b>  | PAED. TRACHEOSTOMY TUBE 5.5MM STANDARD FLEXTEND PLUS        | 3853464 | 4399192 |
| <b>60PFSS35</b> | 3.5MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE       | 3840073 | 4393415 |
| <b>60PFSS40</b> | 4.0MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE       | 3853472 | 4399203 |
| <b>60SN030</b>  | 3.0 UNCUFFED NEONATAL TRACHEOSTOMY TUBE                     | 3874310 | 4395805 |
| <b>60SP030</b>  | 3.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE                    | 3853491 | 4400704 |
| <b>60SP035</b>  | 3.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE                    | 3840044 | 4393429 |
| <b>60SP040</b>  | 4.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE                    | 3840061 | 4389933 |
| <b>60SP045</b>  | 4.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE                    | 3840064 | 4399221 |
| <b>60SP050</b>  | 5.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE                    | 3840086 | 4400710 |
| <b>60SP055</b>  | 5.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE                    | 3868322 | 4399223 |
| <b>65N025</b>   | NEONATAL TRACHEOSTOMY TUBE                                  | 3949029 | 4383590 |
| <b>65N030</b>   | NEONATAL TRACHEOSTOMY TUBE                                  | 3917999 | 4348373 |
| <b>65N035</b>   | NEONATAL TRACHEOSTOMY TUBE                                  | 3871033 | 4389861 |
| <b>65N040</b>   | NEONATAL TRACHEOSTOMY TUBE                                  | 3871068 | 4348376 |
| <b>65P025</b>   | PAED. TRACHEOSTOMY TUBE 2.5MM AIRE-CUF                      | 3897888 | 4400619 |
| <b>65P030</b>   | PAED. TRACHEOSTOMY TUBE 3.0MM AIRE-CUF                      | 3880701 | 4388089 |
| <b>65P035</b>   | PAED. TRACHEOSTOMY TUBE 3.5MM AIRE-CUF                      | 3864229 | 4395735 |
| <b>65P040</b>   | PAED. TRACHEOSTOMY TUBE 4.0MM AIRE-CUF                      | 3853369 | 4383591 |
| <b>65P045</b>   | PAED. TRACHEOSTOMY TUBE 4.5MM AIRE-CUF                      | 3868312 | 4400620 |
| <b>65P050</b>   | PAED. TRACHEOSTOMY TUBE 5.0MM AIRE-CUF                      | 3868226 | 4388090 |
| <b>65P055</b>   | PAED. TRACHEOSTOMY TUBE 5.5MM AIRE-CUF                      | 3840082 | 4400621 |
| <b>65SP025</b>  | 2.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE                    | 4016047 | 4389864 |
| <b>65SP030</b>  | 3.0 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE                    | 4035682 | 4348392 |
| <b>65SP035</b>  | 3.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE                    | 3868192 | 4389865 |
| <b>65SP040</b>  | 4.0 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE                    | 3897869 | 4369534 |
| <b>65SP045</b>  | 4.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE                    | 3955777 | 4399124 |
| <b>65SP050</b>  | 5.0 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE                    | 3868214 | 4399125 |
| <b>65SP055</b>  | 5.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE                    | 3897865 | 4353066 |
| <b>67N025</b>   | TTS NEONATAL TRACH TUBE                                     | 3894899 | 4400622 |
| <b>67N030</b>   | TTS NEONATAL TRACH TUBE                                     | 3853378 | 4399126 |
| <b>67N035</b>   | TTS NEONATAL TRACH TUBE                                     | 3868245 | 4395736 |
| <b>67N040</b>   | TTS NEONATAL TRACHY TUBE 4.0MMTIGHT TO SHAFT CUFF           | 3877658 | 4380068 |
| <b>67NFP25</b>  | NEONATAL TRACHEOSTOMY TUBE 2.5 TTS FLEXTEND V FLANGE        | 3936586 | 4334881 |
| <b>67NFP30</b>  | NEONATAL TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND V FLANGE        | 3853379 | 4380994 |
| <b>67NFPS25</b> | NEONATAL TRACHEOSTOMY TUBE 2.5 TTS FLEXTEND STRAIGHT FLANGE | 3853382 | 4395738 |
| <b>67NFPS30</b> | NEONATAL TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND STRAIGHT FLANGE | 3853383 | 4400623 |
| <b>67P025</b>   | TTS PEDIATRIC TRACH TUBE                                    | 3880708 | 4395744 |

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|-----------------|-------------------------------------------------------------------|---------|---------|
| <b>67P030</b>   | TTS PEDIATRIC TRACH TUBE                                          | 3853386 | 4400626 |
| <b>67P035</b>   | TTS PEDIATRIC TRACH TUBE                                          | 3853387 | 4399129 |
| <b>67P040</b>   | TTS PEDIATRIC TRACH TUBE                                          | 3853388 | 4400627 |
| <b>67P045</b>   | TTS PEDIATRIC TRACH TUBE                                          | 3853389 | 4400628 |
| <b>67P050</b>   | TTS PEDIATRIC TRACH TUBE                                          | 3802119 | 4399132 |
| <b>67P055</b>   | TTS PEDIATRIC TRACH TUBE                                          | 3853393 | 4400629 |
| <b>67PFP60</b>  | PEDIATRIC TRACHEOSTOMY TUBE 6.0 TTS FLEXTEND PLUS V FLANGE        | 3802151 | 4388112 |
| <b>67PFPS40</b> | PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND PLUS STRAIGHT FLANGE | 3853396 | 4399133 |
| <b>67PFPS60</b> | PEDIATRIC TRACHEOSTOMY TUBE 6.0 TTS FLEXTEND PLUS STRAIGHT FLANGE | 3802149 | 4400634 |
| <b>67PFS30</b>  | PEDIATRIC TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND V NECK               | 3853403 | 4400635 |
| <b>67PFS35</b>  | PEDIATRIC TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND V NECK               | 3853405 | 4399138 |
| <b>67PFS40</b>  | PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND V NECK               | 3835787 | 4399139 |
| <b>67PFS45</b>  | PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND V NECK               | 3861137 | 4399140 |
| <b>67PFS50</b>  | PEDIATRIC TRACHEOSTOMY TUBE 5.0 TTS FLEXTEND V NECK               | 3868275 | 4393394 |
| <b>67PFS55</b>  | PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND V NECK               | 3853408 | 4399141 |
| <b>67PFSS40</b> | PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND STRAIGHT NECK        | 3840066 | 4399149 |
| <b>67SN035</b>  | 3.5 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE                         | 3861151 | 4388146 |
| <b>67SP055</b>  | 5.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE                        | 3874309 | 4400657 |