

# Rapid Consensus: Clinical risk stratification tool during Smiths Bivona<sup>®</sup> Tracheostomy paediatric range supply disruption – 2<sup>nd</sup> edition, June 2022.

Circulated by:

Expert Working Group, representing the British Association for Paediatric Otolaryngology, the National Tracheostomy Safety Project, and the British Laryngological Association.

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## Context

In February 2022, an expert clinical working group comprised of representatives from the British Association for Paediatric Otolaryngology, and the National Tracheostomy Safety Project convened on two occasions to agree a consensus on the clinical actions to be taken in response to the shortage of Smiths Medical Bivona<sup>®</sup> paediatric tracheostomy products.

The production of these products was suspended in 2022, due to a raw material shortage, and there had been constraints on these products since the autumn of 2021. Given that the stock position was critical on several product lines and low levels on many other sizes ([Important Customer Notice](#)). It was felt that utilisation of the remaining supply needed to be rationalised, as it was unclear when the expected recovery would be.

From February through to April 2022 there were products arriving into the UK via NHS Supply Chain that were manufactured prior to the line shut down in February 2022. However, in May 2022 a period has been reached where no new supply is incoming until the new stock produced since restarting manufacturing starts to reach the UK. It is anticipated that new stock will arrive in June/July 2022, however full recovery to pre-disruption levels of stock and production is not expected until quarter 1 of 2023-24.

This necessitates a change in practice in the choice of tracheostomy products for children. It is important that affected families and their carers are engaged with and involved in any clinical decisions taken as a result of this issue. In February 2022, the Royal College of Paediatrics and Child Health, Well Child UK, and Together for Short Lives were briefed of the supply constraints. There are other paediatric tracheostomy products available (see [appendix A](#)). These will require clinical assessment, liaison with clinical specialists and review of the suitability of the device with the patient and their families and or carers before using.

This document has been refreshed and updated and has been written to provide support to clinicians who will be responsible for offering clinical advice to their patients, and their families and carers. An expert national clinical working group reconvened in May 2022. This group is made up of consultant paediatric otolaryngologists representing the [British Association of Paediatric Otolaryngology](#), [British Laryngological Association](#), and those with specialist expertise in this field, including senior clinical nurse specialists, working in regional and national networks including

the [National Tracheostomy Safety Project](#), the results of the consensus are to make the recommendations below.

The principles used in the development of this document are to support children and young people and their families, regardless of gender, ethnicity, or socioeconomic status.

## **Bivona<sup>®</sup> Tracheostomy**

The Bivona<sup>®</sup> tracheostomy tube range are intended to provide direct airway access for a tracheotomised patient for up to 29 days. They may be reprocessed and sterilised for single patient use up to 5 times (see manufacturer's guidance in [appendix B](#)). Local protocols for methods of decontamination should be in place.

To reduce the risk of tubes blocking and necessitating earlier changes, vigilant secretion management is required with regular nebulisation and suctioning. Good documentation is required to ensure that the number of times a tube has been reprocessed/sterilised is recorded to prevent inappropriate disposal.

The Bivona<sup>®</sup> FlexTend<sup>™</sup> products allow ventilation connections to sit away from the chin in neonates, infants or children who require this, or neonates, infants or children with a short neck reducing the risk of pressure sores on the chin and improving patient comfort.

## **Clinical risk stratification**

- 1. Patients with established tracheostomy stomas using Bivona<sup>®</sup> tubes in the community.***

***At the next tube change or earlier, children with established tracheostomies should be assessed for suitability to use an alternative tracheostomy device and provided with this unless the clinical consensus is that using an alternative device will be harmful.***

***Available Bivona<sup>®</sup> devices should be prioritised for children that are unsuitable for a switch to a new device i.e. not tolerating a new type of tube or for anatomical reasons.***

All patients currently established on a Bivona<sup>®</sup> tracheostomy device should be reviewed at or before their next tube change to re-evaluate the need for Bivona<sup>®</sup> device and consider switching to an alternative device. If a child with an established tracheostomy has adequate (around 3 months) stock at home, consider reviewing for a change of device at a later date.

Community teams caring for children with tracheostomies in the community, will need to review and assess children for the suitability of alternative devices. This should be done in communication with specialist paediatric ENT/ Long Term Ventilation teams. Local and regional networks can facilitate this discussion and the potential requirement for an outpatient appointment for the device to be changed.

There will be some patients for whom an alternative to their existing tube is undesirable. This will mainly be due to lack of suitable alternative in terms of diameter, length and curvature of the tube, but other factors may also come into play. In these situations, as long as the Bivona<sup>®</sup> tube is available, it can continue to be used, but at each tube change, a reassessment should be performed to consider alternatives.

It is understood that switching children in the community to a new device, may require training for their parents, families and carers in the use cleaning and maintenance of the new devices. However, this mitigation would allow the limited available stock to be utilised for children that are unable to be moved to a new device for clinical reasons such as airway and neck anatomy, non-tolerance, risk of disconnection from long-term ventilation.

Although children and their families should have a spare tube(s) available in accordance with local policy; community teams, should aim to hold further spares tubes locally which can be allocated according to need, and avoid overstocking at an individual level. At each community team contact stock levels should be checked. This method may allow more use of local mutual aid during the most constrained periods of the disruption.

Any change of device will require clinical assessment, as these products have varying lengths, curvature, flanges, and external diameters for example Shiley™ devices have some different diameter measurements to the Bivona® devices. A Bivona® tracheostomy tube product list mapped to the nearest alternative devices has been provided in [appendix A](#). To note, there have been challenges with the KAPITEX® production line (see [Important Customer Notice \(Kapitex\)](#)). The most noticeable differences are present when comparing TRACOE® Mini 355 uncuffed devices with Bivona® FlexTend™ or Shiley™ tubes (tables 3 and 4, [appendix A](#)).

There is recognition that a change of device may require re-evaluation in clinic and a tracheoscopy may be appropriate in some cases. Local operational delivery networks are advised to determine the best approach to take in their area(s); accepting that each patient should be assessed on an individual basis.

Clinical judgement should be applied when assessing whether it is appropriate and safe to use an alternative product. These products include:

- Shiley™ Devices (NCF, NEF, PEF, PELF, PCF, PLCF) (+/- TRACOE® Mini extension piece).
- TRACOE® Silcosoft, and TRACOE® Mini ® (+/- TRACOE® Mini extension piece).

Any changes will need to involve clear communication with patients and their families and or carers and their usual clinical teams. When changing devices, clinicians should practice shared decision making in accordance with best practice, and ensure that

patients and their families are fully informed of the reason for a change of device, the risks and benefits of a new device, and consent to this. Extra support may be needed for patients, families and their carers during this transition.

### *Clinical Procurement*

For those children, where the desired device is not available locally, it is proposed that mutual aid is utilised across clinical networks (e.g. Surgery in Children, Paediatric Critical Care, and Long Term Ventilation Operational Delivery Networks) this process aims to maximize the possibility of procuring the right device for those children that need a specific Bivona<sup>®</sup> device, and maximise the availability of all tracheostomy tubes nationally. If through a mutual aid request (locally, and regionally) a device is not sourced, then a clinical request can be submitted through NHS Supply Chain, where necessary this will be reviewed by clinical experts and every effort will be made to get a device where available. There may be situations where despite these efforts this is not possible. This model of procurement will be extended to devices outside the Bivona<sup>®</sup> tracheostomy range, if and when required. When seeking a KAPITEX<sup>®</sup> device, it will be necessary to order directly through the manufacturers, the current anticipated lead time on an order is 60 days.

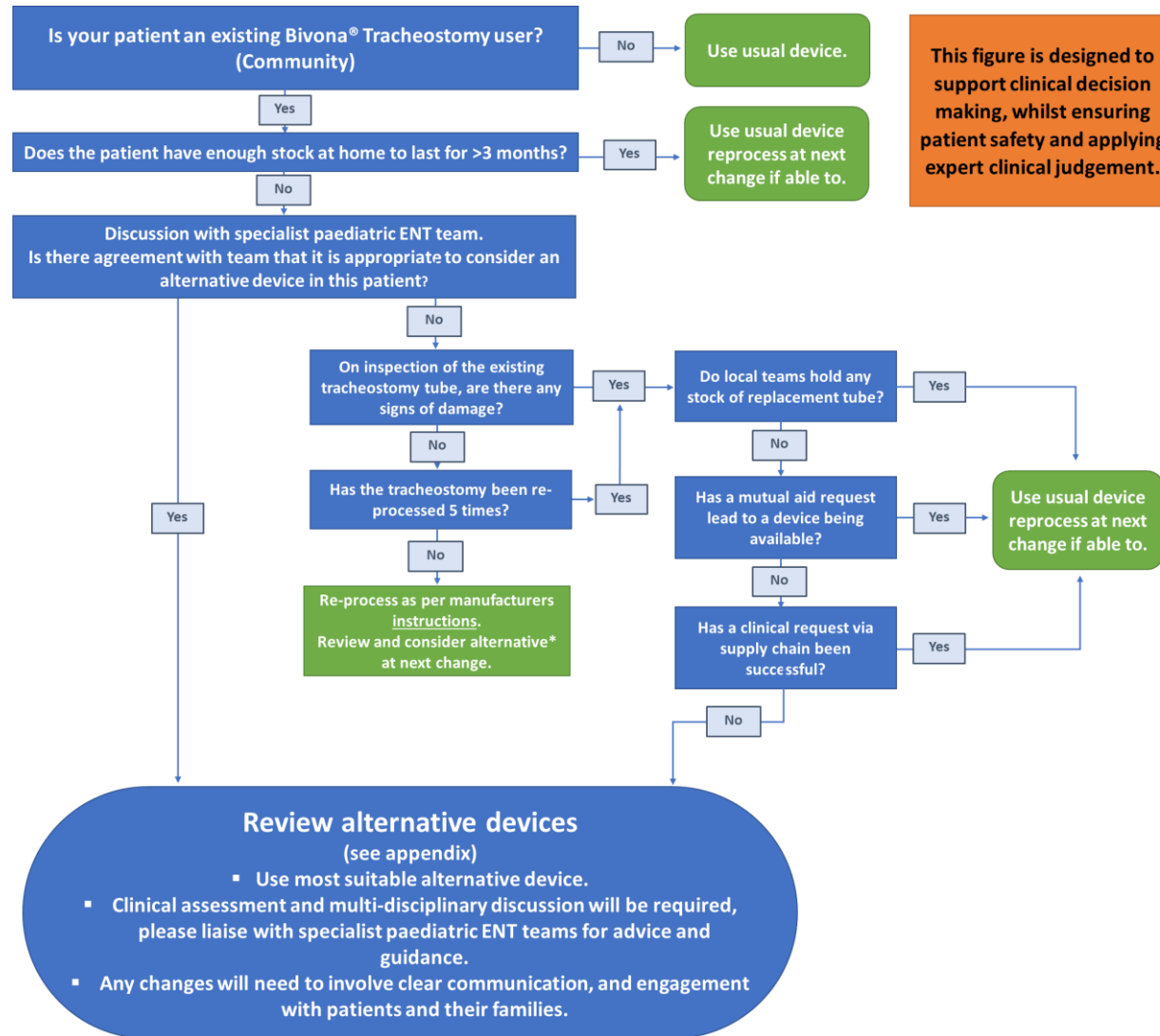
### *Additional considerations*

- If you are unable to find a different tube with the exact same measurements, or the preference is to keep same device then clinical discussion surrounding appropriate change of range, type, for size should be discussed between clinical teams.
- If a tube type is changed, associated documentation and emergency guidelines will need to be updated as per local policy.
- Cleaning and reprocessing guidance (where applicable) is outlined in [appendix B](#), guidance varies and manufacturer guidance and literature should be directly reviewed by relevant staff, and explained and communicated to parents and carers.

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- The decision tree below should be applied alongside independent and expert clinical judgement.

**Figure 1. Flowchart for patients with established tracheostomy stomas using Bivona® tubes in the community.**





## ***2. Patients who require a new tracheostomy***

***New patients requiring a tracheostomy should be fitted with an alternative device to the Bivona® tracheostomy range.***

***The products that are available for new patients that should be utilised are Shiley™ NCF, NEF, PEF, PELF, PCF, PLCF, with or without a TRACOE® mini extension piece or where available, KAPITEX® TRACOE® Silcosoft | KAPITEX® TRACOE® Mini | with or without a TRACOE® mini extension piece ([appendix A](#)).***

Neonates, infants or children requiring a tracheostomy will each have unique anatomical considerations, it is important that all due consideration is given to an alternate available device over Bivona® products first. It is understood however the clinical indication may mean that a Bivona® device is the first preference. The dimension comparison between Bivona® and Shiley™ means that no specific problem should be encountered when using Shiley™ tubes for children who have had a new tracheostomy ([appendix A](#)). Differences do become more apparent when the cuffless paediatric and neonatal Bivona® FlexTend™ tubes were considered and are compared to Shiley™ and TRACOE® mini 355 uncuffed tubes, these are outlined in tables 3 and 4.

For those children, where the desired device is not available locally, it is proposed that mutual aid is utilised across clinical networks (e.g. Surgery in Children, Paediatric Critical Care, and Long Term Ventilation Operational Delivery Networks) to minimise the numbers of children in the community needing to change their usual device. If through a mutual aid request a device is not sourced, then a clinical request can be submitted through NHS Supply Chain, where necessary this will be reviewed by clinical experts and every effort will be made to procure a device. There may be situations where despite these efforts this is not possible due to lack of stock availability held in NHS Supply Chain or by the supplier/manufacturer. This model of procurement can be extended to devices outside the Bivona® tracheostomy range. When seeking a KAPITEX® device, it will be necessary to order directly through the manufacturers, the current anticipated lead time on an order is 60 days. Further

updates on the supply position of the KAPITEX® production lines can be found via this [Important Customer Notice \(Kapitex\)](#).

Good tracheostomy care should include vigilant secretion management and caring for the tube as per manufacturers guidelines. Cleaning and reprocessing guidance (where applicable) is outlined in [appendix B](#), guidance varies and manufacturer guidance and literature should be directly reviewed by relevant staff and explained and communicated to parents and carers. To note the Shiley™ devices can be used for up to 29 days but cannot be reprocessed, whereas Bivona devices can be processed up to 5 times.

### **Discharge preparation**

#### ***You may wish to review your parent/carer training programme***

Given the low stock levels and increased need for alternative devices across the system, parent training may need to be reviewed. Please consider using simulation for early parent/carer training. If discharge is not imminent then consider delaying tube changes (unless due or clinically required).

### **Appendices:**

#### **Appendix A**

#### **Alternative Devices**

**Shiley™ Neonatal and Paediatric Tracheostomy Tubes:** A product guide brochure can be found [here](#). Note, there has recently been a significant change to the Shiley Tracheostomy Product lines

**KAPITEX® Tracoe® Mini, and Tracoe® Silcosoft:** Product links can be found at: [TRACOE® Silcosoft | KAPITEX®](#) , [TRACOE® Mini | Kapitex®](#) and [TRACOE® mini extension piece | KAPITEX®](#)

## Tables of nearest alternative devices

Please note text in red highlights the differences in the outer diameter (OD), whether device is V-flange or straight, and / or length of the tracheostomy tubes.

\*MPC- Manufacturer's product code.

### 1. Cuffless neonatal tracheostomy tubes

Size/ inner diameter (mm)	Bivona® uncuffed neonatal tracheostomy tubes				TRACOE® Silcosoft® 360 uncuffed for neonates				TRACOE® mini 350 uncuffed for neonates				Shiley™ neonatal tracheostomy tubes			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	60N025	4.0	30.0	V-flange	TRSIL6025	4.4	30.0	Straight	TRTRA4001	3.6	30.0	Straight	2.5NEF	4.2	30	V-flange
2.5	60SN025	4.0	30.0	Straight	TRSIL6025	4.4	30.0	Straight	TRTRA4001	3.6	30.0	Straight	2.5NEF	4.2	30	V-flange
3.0	60N030	4.7	32.0	V-flange	TRSIL6030	4.7	32.0	Straight	TRTRA4002	4.3	32.0	Straight	3.0NEF	4.8	30	V-flange
3.0	60SN030	4.7	32.0	Straight	TRSIL6030	4.7	32.0	Straight	TRTRA4002	4.3	32.0	Straight	3.0NEF	4.8	30	V-flange
3.5	60N035	5.3	34.0	V-flange	TRSIL6035	5.4	34.0	Straight	TRTRA4003	5	34.0	Straight	3.5NEF	5.4	32	V-flange
3.5	60SN035	5.3	34.0	Straight	TRSIL6035	5.4	34.0	Straight	TRTRA4003	5	34.0	Straight	3.5NEF	5.4	32	V-flange
4.0	60N040	6.0	36.0	V-flange	TRSIL6040	6.0	36.0	Straight	TRTRA4004	5.6	36.0	Straight	4.0NEF	6	34	V-flange
4.0	60SN040	6.0	36.0	Straight	TRSIL6040	6.0	36.0	Straight	TRTRA4004	5.6	36.0	Straight	4.0NEF	6	34	V-flange

## 2. Cuffless paediatric tracheostomy tubes

Size/ inner diameter (mm)	Bivona® uncuffed pediatric tracheostomy tubes				TRACOE® Silcosoft® 370 uncuffed for children				TRACOE® mini 355 uncuffed for children				Shiley™ paediatric tracheostomy tubes			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	60P025	4.0	38.0	V-flange	TRSIL7025	4.4	38.0	Straight	TRTRA4005	3.6	32.0	Straight	2.5PEF	4.2	39.0	V-flange
2.5	60SP025	4.0	38.0	Straight	TRSIL7025	4.4	38.0	Straight	TRTRA4005	3.6	32.0	Straight	2.5PEF	4.2	39.0	V-flange
3.0	60P030	4.7	39.0	V-flange	TRSIL7030	4.7	39.0	Straight	TRTRA4006	4.3	36.0	Straight	3.0PEF	4.8	39.0	V-flange
3.0	60SP030	4.7	39.0	Straight	TRSIL7030	4.7	39.0	Straight	TRTRA4006	4.3	36.0	Straight	3.0PEF	4.8	39.0	V-flange
3.5	60P035	5.3	40.0	V-flange	TRSIL7035	5.4	40.0	Straight	TRTRA4007	5.0	40.0	Straight	3.5PEF	5.4	40.0	V-flange
3.5	60SP035	5.3	40.0	Straight	TRSIL7035	5.4	40.0	Straight	TRTRA4007	5.0	40.0	Straight	3.5PEF	5.4	40.0	V-flange
4.0	60P040	6.0	41.0	V-flange	TRSIL7040	6.0	41.0	Straight	TRTRA4008	5.6	44.0	Straight	4.0PEF	6.0	41.0	V-flange
4.0	60SP040	6.0	41.0	Straight	TRSIL7040	6.0	41.0	Straight	TRTRA4008	5.6	44.0	Straight	4.0PEF	6.0	41.0	V-flange
4.5	60P045	6.7	42.0	V-flange	TRSIL7045	6.6	42.0	Straight	TRTRA4009	6.3	48.0	Straight	4.5PEF	6.7	42.0	V-flange
4.5	60SP045	6.7	42.0	Straight	TRSIL7045	6.6	42.0	Straight	TRTRA4009	6.3	48.0	Straight	4.5PEF	6.7	42.0	V-flange
5.0	60P050	7.3	44.0	V-flange	TRSIL7050	7.3	44.0	Straight	TRTRA4010	7.0	50.0	Straight	5.0PEF	7.3	44.0	V-flange
5.0	60SP050	7.3	44.0	Straight	TRSIL7050	7.3	44.0	Straight	TRTRA4010	7.0	50.0	Straight	5.0PEF	7.3	44.0	V-flange
5.5	60P055	8.0	46.0	V-flange	TRSIL7055	8.4	46.0	Straight	TRTRA4011	7.6	55.0	Straight	5.5PEF	7.9	46.0	V-flange
5.5	60SP055	8.0	46.0	Straight	TRSIL7055	8.4	46.0	Straight	TRTRA4011	7.6	55.0	Straight	5.5PEF	7.9	46.0	V-flange

### 3. Cuffless neonatal FlexTend™ tracheostomy tubes

Size/ inner diameter (mm)	Bivona® uncuffed neonatal FlexTend™ plus tracheostomy tubes				TRACOE® Silcosoft® 361 PL uncuffed for neonates and infants				TRACOE® mini 350 uncuffed for neonates +/- TRACOE® mini extension piece				Shiley™ neonatal cuffless tracheostomy tubes +/- TRACOE® mini extension piece			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	60NFP25	4.0	30.0	V- flange	TRSIL6125	4.4	30.0	Straight	TRTRA4001	3.6	30.0	Straight	2.5NEF	4.2	30	V- flange
2.5	60SNFPS25	4.0	30.0	Straight	TRSIL6125	4.4	30.0	Straight	TRTRA4001	3.6	30.0	Straight	2.5NEF	4.2	30	V- flange
3.0	60NFP30	4.7	32.0	V- flange	TRSIL6130	4.7	32.0	Straight	TRTRA4002	4.3	32.0	Straight	3.0NEF	4.8	30	V- flange
3.0	60SNFPS30	4.7	32.0	Straight	TRSIL6130	4.7	32.0	Straight	TRTRA4002	4.3	32.0	Straight	3.0NEF	4.8	30	V- flange
3.5	60NFP35	5.3	34.0	V- flange	TRSIL6135	5.4	34.0	Straight	TRTRA4003	5	34.0	Straight	3.5NEF	5.4	32	V- flange
3.5	60SNFPS35	5.3	34.0	Straight	TRSIL6135	5.4	34.0	Straight	TRTRA4003	5	34.0	Straight	3.5NEF	5.4	32	V- flange
4.0	60NFP40	6.0	36.0	V- flange	TRSIL6140	6.0	36.0	Straight	TRTRA4004	5.6	36.0	Straight	4.0NEF	6	34	V- flange
4.0	60SNFPS40	6.0	36.0	Straight	TRSIL6140	6.0	36.0	Straight	TRTRA4004	5.6	36.0	Straight	4.0NEF	6	34	V- flange

#### 4. Cuffless paediatric FlexTend™ tracheostomy tubes

Size/ inner diameter (mm)	Bivona® uncuffed paediatric flextend plus standard tracheostomy tubes				TRACOE® Silcosoft® 371 PL uncuffed for children				TRACOE® mini 355 uncuffed for children +/- TRACOE® mini extension piece				Shiley™ paediatric cuffless tracheostomy tubes +/- TRACOE ® mini extension piece			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	60PFS			V-	TRSIL71			Straig	TRTRA40			Straig	2.5PE			V-
	25	4.0	38.0	flange	25	4.4	38.0	ht	05	3.6	32.0	ht	F	4.2	39.0	flange
2.5	60PFS			Straig	TRSIL71			Straig	TRTRA40			Straig	2.5PE			V-
	S25	4.0	38.0	ht	25	4.4	38.0	ht	05	3.6	32.0	ht	F	4.2	39.0	flange
3.0	60PFS			V-	TRSIL71			Straig	TRTRA40			Straig	3.0PE			V-
	30	4.7	39.0	flange	30	4.7	39.0	ht	06	4.3	36.0	ht	F	4.8	39.0	flange
3.0	60PFS			Straig	TRSIL71			Straig	TRTRA40			Straig	3.0PE			V-
	S30	4.7	39.0	ht	30	4.7	39.0	ht	06	4.3	36.0	ht	F	4.8	39.0	flange
3.5	60PFS			V-	TRSIL71			Straig	TRTRA40			Straig	3.5PE			V-
	35	5.3	40.0	flange	35	5.4	40.0	ht	07	5.0	40.0	ht	F	5.4	40.0	flange
3.5	60PFS			Straig	TRSIL71			Straig	TRTRA40			Straig	3.5PE			V-
	S35	5.3	40.0	ht	35	5.4	40.0	ht	07	5.0	40.0	ht	F	5.4	40.0	flange
4.0	60PFS			V-	TRSIL71			Straig	TRTRA40			Straig	4.0PE			V-
	40	6.0	41.0	flange	40	6.0	41.0	ht	08	5.6	44.0	ht	F	6.0	41.0	flange
4.0	60PFS			Straig	TRSIL71			Straig	TRTRA40			Straig	4.0PE			V-
	S40	6.0	41.0	ht	40	6.0	41.0	ht	08	5.6	44.0	ht	F	6.0	41.0	flange
4.5	60PFS			V-	TRSIL71			Straig	TRTRA40			Straig	4.5PE			V-
	45	6.7	42.0	flange	45	6.6	42.0	ht	09	6.3	48.0	ht	F	6.7	42.0	flange
4.5	60PFS			Straig	TRSIL71			Straig	TRTRA40			Straig	4.5PE			V-
	S45	6.7	42.0	ht	45	6.6	42.0	ht	09	6.3	48.0	ht	F	6.7	42.0	flange
5.0	60PFS			V-	TRSIL71			Straig	TRTRA40			Straig	5.0PE			V-
	50	7.3	44.0	flange	50	7.3	44.0	ht	10	7.0	50.0	ht	F	7.3	44.0	flange
5.0	60PFS			Straig	TRSIL71			Straig	TRTRA40			Straig	5.0PE			V-
	S50	7.3	44.0	ht	50	7.3	44.0	ht	10	7.0	50.0	ht	F	7.3	44.0	flange
5.5	60PFS			V-	TRSIL71			Straig	TRTRA40			Straig	5.5PE			V-
	55	8.0	46.0	flange	55	8.4	46.0	ht	11	7.6	55.0	ht	F	7.9	46.0	flange
5.5	6SPF			Straig	TRSIL71			Straig	TRTRA40			Straig	5.5PE			V-
	SS55	8.0	46.0	ht	55	8.4	46.0	ht	11	7.6	55.0	ht	F	7.9	46.0	flange

### 5. Cuffless paediatric FlexTend™ plus extra length tracheostomy tubes

Size/ inner diameter (mm)	Bivona® uncuffed paediatric FlexTend™ plus extra length tracheostomy tubes				TRACOE® mini 355 uncuffed for children +/- TRACOE® mini extension piece				Shiley™ paediatric tracheostomy extra-long cuffless tubes +/- TRACOE® mini extension piece			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
4.0	60PFP40	6.0	44.0	V-flange	TRTRA4008	5.6	44.0	Straight				
4.0	60PFPS40	6.0	44.0	Straight	TRTRA4008	5.6	44.0	Straight				
4.5	60PFP45	6.7	48.0	V-flange	TRTRA4009	6.3	48.0	Straight				
4.5	60PFPS45	6.7	48.0	Straight	TRTRA4009	6.3	48.0	Straight				
5.0	60PFP50	7.3	50.0	V-flange	TRTRA4010	7.0	50.0	Straight	5.0PELF	7.3	50.0	V-flange
5.0	60PFPS50	7.3	50.0	Straight	TRTRA4010	7.0	50.0	Straight	5.0PELF	7.3	50.0	V-flange
5.5	60PFP55	8.0	52.0	V-flange	TRTRA4011	7.6	55.0	Straight	5.5PELF	7.9	52.0	V-flange
5.5	60PFPS55	8.0	52.0	Straight	TRTRA4011	7.6	55.0	Straight	5.5PELF	7.9	52.0	V-flange
6.0	60PFP60	8.7	56.0	V-flange	TRTRA4012	8.4	62.0	Straight	6.0PELF	8.5	54.0	V-flange
6.0	60PFPS60	8.7	56.0	Straight	TRTRA4011	7.6	62.0	Straight	6.0PELF	8.5	54.0	V-flange

6. Tight to shaft (TTS) neonatal tracheostomy tubes

Size/ inner diameter (mm)	Bivona® TTS cuffed neonatal tracheostomy tubes				TRACOE® Silcosoft® 362 H2O cuff for neonates and infants				Shiley™ neonatal tracheostomy tubes with taperguard cuff (air)			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	67N025	4.0	30.0	V-flange	TRSIL6225	4.4	30.0	Straight	2.5NCF	4.2	30	V-flange
2.5	67SN025	4.0	30.0	Straight	TRSIL6225	4.4	30.0	Straight	2.5NCF	4.2	30	V-flange
3.0	67N030	4.7	32.0	V-flange	TRSIL6230	4.7	32.0	Straight	3.0NCF	4.8	30	V-flange
3.0	67SN030	4.7	32.0	Straight	TRSIL6230	4.7	32.0	Straight	3.0NCF	4.8	30	V-flange
3.5	67N035	5.3	34.0	V-flange	TRSIL6235	5.4	34.0	Straight	3.5NCF	5.4	32	V-flange
3.5	67SN035	5.3	34.0	Straight	TRSIL6235	5.4	34.0	Straight	3.5NCF	5.4	32	V-flange
4.0	67N040	6.0	36.0	V-flange	TRSIL6240	6.0	36.0	Straight	4.0NCF	6	34	V-flange
4.0	67SN040	6.0	36.0	Straight	TRSIL6240	6.0	36.0	Straight	4.0NCF	6	34	V-flange



## 7. Tight to shaft (TTS) paediatric tracheostomy tubes

Size/ inner diameter (mm)	Bivona® TTS cuffed paediatric tracheostomy tubes				TRACOE® Silcosoft® 372 H2O cuff for children				Shiley™ paediatric tracheostomy tubes with taperguard cuff (air)			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	67P025	4.0	38.0	V-flange	TRSIL7225	4.4	38.0	Straight	2.5PCF	4.2	39.0	V-flange
2.5	67SP025	4.0	38.0	Straight	TRSIL7225	4.4	38.0	Straight	2.5PCF	4.2	39.0	V-flange
3.0	67P030	4.7	39.0	V-flange	TRSIL7230	4.7	39.0	Straight	3.0PCF	4.8	39.0	V-flange
3.0	67SP030	4.7	39.0	Straight	TRSIL7230	4.7	39.0	Straight	3.0PCF	4.8	39.0	V-flange
3.5	67P035	5.3	40.0	V-flange	TRSIL7235	5.4	40.0	Straight	3.5PCF	5.4	40.0	V-flange
3.5	67SP035	5.3	40.0	Straight	TRSIL7235	5.4	40.0	Straight	3.5PCF	5.4	40.0	V-flange
4.0	67P040	6.0	41.0	V-flange	TRSIL7240	6.0	41.0	Straight	4.0PCF	6.0	41.0	V-flange
4.0	67SP040	6.0	41.0	Straight	TRSIL7240	6.0	41.0	Straight	4.0PCF	6.0	41.0	V-flange
4.5	67P045	6.7	42.0	V-flange	TRSIL7245	6.6	42.0	Straight	4.5PCF	6.7	42.0	V-flange
4.5	67SP045	6.7	42.0	Straight	TRSIL7245	6.6	42.0	Straight	4.5PCF	6.7	42.0	V-flange
5.0	67P050	7.3	44.0	V-flange	TRSIL7250	7.3	44.0	Straight	5.0PCF	7.3	44.0	V-flange
5.0	67SP050	7.3	44.0	Straight	TRSIL7250	7.3	44.0	Straight	5.0PCF	7.3	44.0	V-flange
5.5	67P055	8.0	46.0	V-flange	TRSIL7255	8.4	46.0	Straight	5.5PCF	7.9	46.0	V-flange
5.5	67SP055	8.0	46.0	Straight	TRSIL7255	8.4	46.0	Straight	5.5PCF	7.9	46.0	V-flange

### 8. FlexTend™ cuffed neonatal tracheostomy tubes

Size/ inner diameter (mm)	Bivona® FlexTend™ TTS cuffed neonatal tracheostomy tubes				TRACOE® Silcosoft® 363 H2O cuff for neonates and infants				Shiley™ neonatal tracheostomy tubes with taperguard cuff (air) +/- Trachoe mini extension piece			
	MPC*	OD (mm)	length (mm)	flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	67NFP25	4.0	30.0	V-flange	TRSIL6325	4.4	30.0	straight	2.5NCF	4.2	30	V-flange
2.5	67NFPS25	4.0	30.0	Straight	TRSIL6325	4.4	30.0	straight	2.5NCF	4.2	30	V-flange
3.0	67NFP30	4.7	32.0	V-flange	TRSIL6330	4.7	32.0	Straight	3.0NCF	4.8	30	V-flange
3.0	67NFPS30	4.7	32.0	Straight	TRSIL6330	4.7	32.0	Straight	3.0NCF	4.8	30	V-flange
3.5	67NFP35	5.3	34.0	V-flange	TRSIL6335	5.4	34.0	Straight	3.5NCF	5.4	32	V-flange
3.5	67NFP035	5.3	34.0	Straight	TRSIL6335	5.4	34.0	Straight	3.5NCF	5.4	32	V-flange
4.0	67NFP40	6.0	36.0	V-flange	TRSIL6340	6.0	36.0	Straight	4.0NCF	6	34	V-flange
4.0	67NFPS40	6.0	36.0	Straight	TRSIL6340	6.0	36.0	Straight	4.0NCF	6	34	V-flange

### 9. FlexTend™ cuffed paediatric tracheostomy tubes

Size/ inner diameter (mm)	Bivona® FlexTend™ TTS cuffed paediatric tracheostomy tubes				TRACOE® Silcosoft® 373 H2O cuff for children				Shiley™ paediatric tracheostomy tubes with taperguard cuff (air) +/- Trachoe mini extension piece			
	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange	MPC*	OD (mm)	Length (mm)	Flange
2.5	67PFS25	4.0	38.0	V-flange	TRSIL7325	4.4	38.0	straight	2.5PCF	4.2	39.0	V-flange
2.5	67PFSS25	4.0	38.0	Straight	TRSIL7325	4.4	38.0	straight	2.5PCF	4.2	39.0	V-flange
3.0	67PFS30	4.7	39.0	V-flange	TRSIL7330	4.7	39.0	Straight	3.0PCF	4.8	39.0	V-flange
3.0	67PFSS30	4.7	39.0	Straight	TRSIL7330	4.7	39.0	Straight	3.0PCF	4.8	39.0	V-flange
3.5	67PFS35	5.3	40.0	V-flange	TRSIL7335	5.4	40.0	Straight	3.5PCF	5.4	40.0	V-flange
3.5	67PFSS35	5.3	40.0	Straight	TRSIL7335	5.4	40.0	Straight	3.5PCF	5.4	40.0	V-flange
4.0	67PFS40	6.0	41.0	V-flange	TRSIL7340	6.0	41.0	Straight	4.0PCF	6.0	41.0	V-flange
4.0	67PFSS40	6.0	41.0	Straight	TRSIL7340	6.0	41.0	Straight	4.0PCF	6.0	41.0	V-flange
4.5	67PFS45	6.7	42.0	V-flange	TRSIL7345	6.6	42.0	Straight	4.5PCF	6.7	42.0	V-flange
4.5	67PFSS45	6.7	42.0	Straight	TRSIL7345	6.6	42.0	Straight	4.5PCF	6.7	42.0	V-flange
5.0	67PFS50	7.3	44.0	V-flange	TRSIL7350	7.3	44.0	Straight	5.0PCF	7.3	44.0	V-flange
5.0	67PFSS50	7.3	44.0	Straight	TRSIL7350	7.3	44.0	Straight	5.0PCF	7.3	44.0	V-flange
5.5	67PFS55	8.0	46.0	V-flange	TRSIL7355	8.4	46.0	Straight	5.5PCF	7.9	46.0	V-flange
5.5	67PFSS55	8.0	46.0	Straight	TRSIL7355	8.4	46.0	Straight	5.5PCF	7.9	46.0	V-flange

### 10. FlexTend™ plus, cuffed tracheostomy tubes

Size/ inner diameter (mm)	Bivona® FlexTend™ TTS plus cuffed tracheostomy tubes				Shiley™ paediatric tracheostomy extra-long with taperguard cuff (air) +/- TRACOE® mini extension piece			
	MPC*	OD (mm)	length (mm)	flange	MPC*	OD (mm)	Length (mm)	Flange
4.0	67PFP40	6.0	44.0	V-flange				
4.0	67PFPS40	6.0	44.0	Straight				
4.5	67PFP45	6.7	48.0	V-flange				
4.5	67PFPS45	6.7	48.0	Straight				
5.0	67PFP50	7.3	50.0	V-flange	5.0PLCF	7.3	50.0	V-flange
5.0	67PFPS50	7.3	50.0	Straight	5.0PLCF	7.3	50.0	V-flange
5.5	67PFP55	8.0	52.0	V-flange	5.5PLCF	7.9	52.0	V-flange
5.5	67PFPS55	8.0	52.0	Straight	5.5PLCF	7.9	52.0	V-flange
6.0	67PFP60	8.7	56.0	V-flange	6.0PLCF	8.5	54.0	V-flange
6.0	67PFPS60	8.7	56.0	Straight	6.0PLCF	8.5	54.0	V-flange

## Appendix B

### Care of Tracheostomy Tubes by manufacturer and products

Please note this is a summary of manufacturers specifications and recommendations, please consult the product literature for exhaustive details before use.

Locally agreed protocol for methods of decontamination must be in place in organisations. Organisations should have standard operating procedures for reprocessing (where applicable) which include documented approval for products to be used and an escalation process in place if there are concerns or issues raised. Organisations will need to ensure staff are trained in cleaning and decontamination processes and hold appropriate competencies for their role. Organisations have a responsibility to systematically identify, assess and monitor all decontamination processes relating to reusable medical devices, ensuring that they are compliant with required standards and processes. Manufacturer's instructions for decontamination must be followed. Please ensure the appropriate Health Technical Memoranda have been referred to and followed in terms of use of washer disinfector and gravity displacement sterilizers. Managers of departments and units will need to add any significant infection prevention and control risks to organisational risk registers. Any significant on-going unresolved risks will need to be identified and discussed at Infection Control Committee or equivalent.

#### ***Bivona FlexTend™ Tubes***

- FlexTend™ Tube improves access in children when in the prone position.
- Keeps the ventilation connections away from under the chin improving comfort and mobility.
- Enables the development of natural head movements in babies with small necks as the tube does not hinder movement.
- These tubes are made of siliconised PVC and are hydrophobic hindering protein adhesion therefore limiting secretion build up. This results in them being routinely changed monthly.
- They may still require emergency changes due to blockages.
- They also can be changed more frequently for training purposes.
- These tubes can also be reprocessed 5 times for single patient use.

- To clean wash in a mild, fragrance free, clear detergent, rinse thoroughly and allow to air dry.
- They have a wire reinforcement providing a flexible tube that conforms with the trachea and resists kinking.

These tubes are not MRI scan compatible

### ***Bivona® Reprocessing guidance***

Product information for the Portex® Bivona® tracheostomy tubes can be found [here](#).

There are many different types of tracheostomy tubes all with slightly different ways to care for them.

### ***Shiley™ Tubes***

- Single use tubes.
- As per manufacturer they can be changed every 29 days, however they can become coated in secretions and require more frequency changes, please refer to local policy.
- They need changing whenever blocked and can be changed more frequently for training purposes.

### ***Kapitex®TRACOE® mini tracheostomy tubes***

- TRACOE® mini tracheostomy tubes for neonates and children consist of a soft and flexible neck flange with two wings and a 15 mm connector as well as a thin-walled, radiopaque, specially curved cannula. Each tube will be delivered with an obturator.
- TRACOE® mini Extension Piece can be placed on all TRACOE® mini tubes. It is particularly indicated for children with a very short neck in order to prevent the opening of the tube from dislocating.
- TRACOE® mini tracheostomy tubes are single patient use but can have multiple uses on one patient.
- Manufacturer recommendations are to use TRACOE® mini tracheostomy tubes for no longer than 14 days.
- Tubes that show even the slightest damages must be replaced.
- TRACOE® mini tracheostomy tubes must not be stored at a temperature of over 50°C and under -20°C.

- Care, Cleaning and Disinfection:
  - The care of TRACOE® mini tubes is based on regular, thorough cleaning.
  - The tubes can be cleaned with normal household means like for example mild detergents.
  - For cleaning TRACOE® mini tubes the manufacturer recommends the use of a complete TRACOE® tube clean cleaning set. The sets include a cleaning tub with mesh insert, cleaning agent, cleaning swabs, and cleaning brush. When cleaning the outer cannula, care must be taken to ensure that the cuff is not damaged. The outer and inner cannulas are placed separately in the mesh insert. This will then be immersed in the cleaning solution in the tub. The best way of removing any secretion deposits inside the cannulas is by using the small or large TRACOE® tube clean cleaning swabs. The cleaning swabs consist of a flexible plastic stick with a fluff-free polyurethane sponge attached to the end. This avoids introducing fluff into the cannula or trachea. For impurities that are difficult to remove, a cleaning brush with a rounded tip and soft bristles should be used. On no account should brushes with a sharp-edged end be used as these can scratch the soft material of the cannulas. After cleaning, rinse the cannulas with tap water or distilled water and let them dry. For further details, see Instructions for Use for TRACOE® tube clean cleaning sets.
  - Disinfection: Since the upper respiratory tract is never without germs – even in healthy persons – the manufacturers do not recommend the use of disinfection. If, however, disinfection appears necessary, TRACOE® medical can provide, on request, a list of tested disinfectants. This list can also be accessed on the website of TRACOE® medical ([www.tracoe.com](http://www.tracoe.com)).

***TRACOE® Silcosoft® tracheostomy tubes for Neonates/Infant and Children***

- TRACOE® Silcosoft® tracheostomy tube is intended to provide direct airway access for a tracheotomized patient up to 29 days.
- It may be reprocessed for single patient use up to 7 times.

- The silicone tracheostomy tube is radiopaque, and wire reinforced. It is available in different diameters and lengths, and in cuffed or uncuffed models. The cuffed model is provided with the cuff deflated and flush with the tube. The obturator is made of plastic or metal depending on the type of tube. The TRACOE® Silcosoft® tracheostomy tube is MR compatible under certain conditions (see manufacturers guidelines).

### ***Cleaning Advice:***

- The tube and obturator must be cleaned before reprocessing and/or reuse. The following instruction for manual cleaning applies to all TRACOE® Silcosoft® models and sizes: The tracheostomy tube should be cleaned immediately after removal from the stoma to prevent drying of soil and contaminants.
  - To clean the tube and obturator, rinse the devices separately under lukewarm (40 °C/104 °F) potable water at least for 3 minutes, until they are visibly clean and free of contaminants/encrustations.
  - Particular attention should be taken to ensure the inside of the tube is thoroughly rinsed. If encrustations are still present after rinsing, soak the device in warm water (up to 65 °C/149 °F) up to 30 minutes and rinse again.
  - Repeat these steps as required until the tube is visually clean. All areas of the tube and obturator should be inspected, in adequate light, to ensure the device is free of contaminants and encrustations.
  - When cleaning, take care not to damage the H2O Cuff.
  - Following the cleaning process, place the tube and obturator on a clean dry towel and air-dry in an area free of airborne contaminants.
  - The tube and obturator are considered dry when there is no visual evidence of residual water. Following the drying process, the tube can be reinserted, or sterilized with steam sterilization.
  - If, after cleaning, the tube and obturator will be disinfected with hot water disinfection, drying is not required.

### ***Reprocessing***

- Organisations have a responsibility to systematically identify, assess and monitor all decontamination processes relating to reusable medical devices,



ensuring that they are compliant with required standards and processes. Please ensure the appropriate Health Technical Memoranda have been referred to and followed in terms of use of washer disinfector and gravity displacement sterilizers.

- Locally agreed protocols for methods of decontamination for in hospital re-use must be in place in organisations.

#### *Hot Water Disinfection (typically used in home care)*

- Fill a pot (with lid) with potable water and place over a heat source until the water is boiling (100 °C/212 °F).
- Place the clean tube and obturator, separately, into the pot of boiling water.
- Immediately cover the pot with a lid and allow the water to continue boiling for 3 minutes. Then carefully remove the pot from the heat source.
- The tube and obturator should remain in the covered pot of water for 30 minutes, at which time the water should be cool.
- Remove the tube by holding the 15 mm connector end, and the obturator by the handle.
- Place the tube and obturator on a clean dry towel and air-dry in an area free of airborne contaminants. The tube and obturator are considered dry when there is no visual evidence of residual water.
- All areas of tube and obturator should be visually inspected, in adequate light, to ensure the device is free of contaminants and there is no visible damage to the devices, e.g. cracks, holes etc.
- Following inspection, the obturator can be inserted in the tube and the device reinserted into the patient.
- If the device is not immediately reinserted into the patient, place in a clean dry container that can be sealed (e.g. lid) to reduce the risk of contamination.

#### *Autoclave Sterilization (Moist Heat/Steam)*

- Place the clean, dry tube and obturator in separate sterilization pouches (use only an approved sterilization pouch).
- Place the tube and obturator for 30 minutes at 121°C (250 °F) in a gravity displacement steam sterilizer, with a minimum drying time of 15 minutes.

- Care must be taken to follow the steam sterilizer's manufacturer instructions for use. Once the device has been sterilized, it can be re-inserted into the patient.
- If the sterilized tube is not used immediately, store the sterilized tube and obturator in their sterilization pouch.

## Appendix C

### Background Information

A child may require a tracheostomy for the following reasons:

- Upper air way obstruction (e.g. a neonate, infant, or child with subglottic stenosis, vocal cord palsy, micrognathia, or haemangioma of the upper airway)
- For ventilation (e.g. a neonate, infant, or child requiring long-term ventilation)
- Aspiration of bronchial secretions (e.g. a child has an ineffective swallow/cough and carries a risk of aspiration and recurrent chest infections.
- Reduction of airway resistance (e.g. to improve ventilation in a neonate, infant, or child and reduce the upper airway resistance experience in inspiration and expiration through upper airways).
- Surgery to upper airway (e.g. a neonate, infant, or child requiring major head and neck surgery)

There are numerous types of tracheostomy tubes which may be chosen to suit a neonate, infant, or child's individual clinical needs and anatomy.

These include (most commonly):

- Uncuffed tubes- made from plastic or silicone consisting of a single tube or an inner and outer tube
- Uncuffed FlexTend™ tubes made of silicone for children that require extra external length
- Low pressure/low volume air filled cuffed tube made of plastic or silicone used to aid ventilation
- A high pressure/low volume tight to shaft (TTS) FlexTend™ cuffed tube made of silicone used for ventilation of children who require extra external length.

A patient is determined to have an established tracheostomy stoma after their first tube change.

As part of a patients' care plan, parents and carers will be trained in managing the tracheostomy. This is key to the child's care in the community and is a milestone for discharging a patient. Parents and carers with babies and children with established tracheostomy stomas in the community are trained to use the fitted device. Further information on the care for children with tracheostomies can be found at the National Tracheostomy Safety Project [here](#).

Neonates, infants, or children with tracheostomies will have emergency equipment available to them including a spare tracheostomy tube of the same size and one size smaller for emergencies.

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