

Urgent Medical Device Recall

Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, and Cuffless: Disposable Inner Cannula or Reusable Inner Cannula

27-March-2023

Dear Purchasing Dept/Risk Managers:

The purpose of this letter is to advise you that Medtronic is initiating a voluntary recall for specific production lots of Shiley™ Adult Flexible Tracheostomy Tubes with TaperGuard™ Cuff and Cuffless with Disposable or Reusable Inner Cannulas. This recall follows reports from customers that the device connector in some instances is not making a secure connection with the 15mm cap and other 15mm circuit components and accessories. You are receiving this letter because Medtronic records indicate that potentially affected devices were shipped to your facility.

Issue Description:

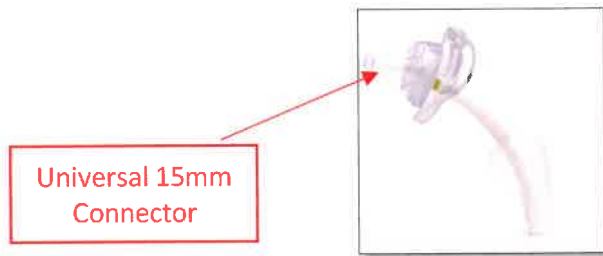
Our investigation of these customer reports identified a manufacturing error, which resulted in a less than specified diameter of the connector component of specific Shiley™ Adult Flexible Tracheostomy Tubes. This resulted in an unsecure connection between the device connector and circuit components, cap or accessories.

Risk to Health:

While no serious patient harm was associated with these devices, dyspnea, a delay to treatment while an alternate device was obtained, and minor tissue injury and bleeding were reported. There may exist the potential for respiratory failure; however, no reports of this occurrence have been reported to Medtronic.

Patient Management:

There are no additional patient management recommendations that should be employed for patients, where potentially affected devices are currently in use or were used. A device affected by this dimensional discrepancy would likely be evident to the practitioner at placement; any 15mm connector of the Shiley™ Adult Flexible Tracheostomy Tube that does not securely attach or stay attached to a cap or accessory should not be used. In this instance, an alternate tracheostomy device should be placed. Please reference Attachment B of this letter for a list of potentially affected devices. Patients with potentially affected devices in use do not need to have their tracheostomy tubes replaced if the current connections are secure. These patients should be monitored in accordance with your medical facility's critical care protocols. Clinical staff should appropriately assess and manage patients for any adverse clinical outcomes.



Product Scope:

Please refer to Attachment B for the list of potentially affected devices.

Actions to be taken:

- Quarantine all unused product from the affected lots of Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, and Cuffless: Disposable Inner Cannula and Reusable Inner Cannula
- See attachment B for guidance on identifying potentially affected devices.
- Return all unused product from the affected lots in your inventory to Medtronic as described on the Customer Confirmation Form.
- Please complete the enclosed Customer Confirmation Form and return it to rs.canfieldactions@medtronic.com even if you **do not** have unused inventory.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected product from the specified lots has been transferred or distributed.

Additional Information:

Medtronic will notify all applicable regulatory agencies about this matter.

As is standard practice, adverse event or quality problems experienced with the use of this product should be reported to your local Medtronic Sales Representative.

We are committed to patient safety and appreciate your prompt attention to this matter. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your local Medtronic Representative.

Sincerely,

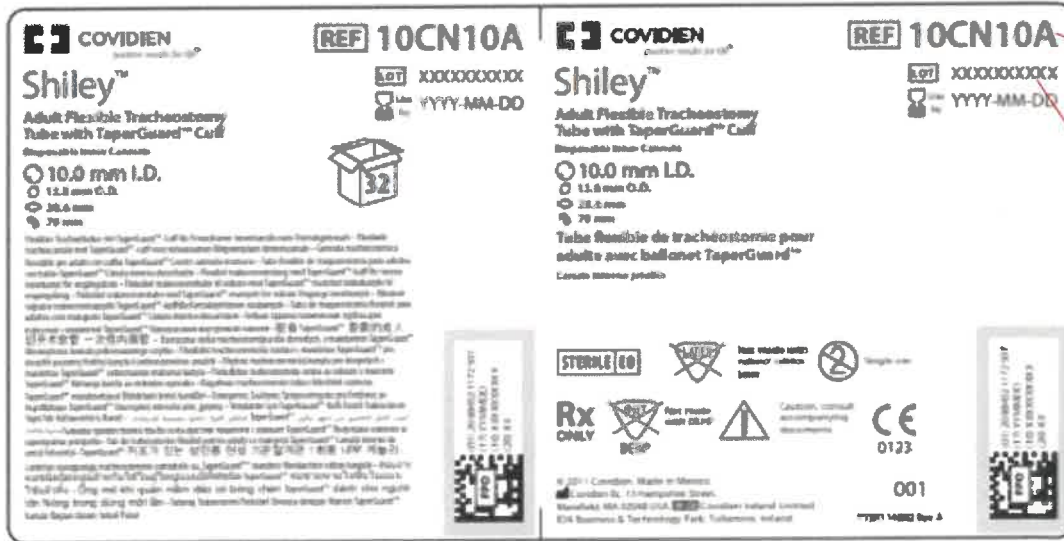
Zachary Zoltek
Manager, Post-Market Vigilance
Medtronic Canada ULC

Enclosures:

- Attachment A: Identifying Affected Devices
- Attachment B: List of Potentially Affected Devices
- Customer Confirmation Form

**Attachment A:
IDENTIFYING POTENTIALLY AFFECTED DEVICES**

Locate product information on product labels in your inventory



Model Number

Lot Number



Model Number

Lot Number

**Attachment B:
LIST OF POTENTIALLY AFFECTED DEVICES**

Item Code/ Model Number	Product Description	GTIN	Affected Lot Numbers					
10CN10H	10CN10H 10.0MM SHILEY CUFFED TRACH CAN	10884521172371	21C0402JZX	21G0457JZX	21I0294JZX	21J1435JZX	21K0275JZX	21K0277JZX
			21D0461JZX	21I0293JZX	21I0552JZX	21J1436JZX	21K0276JZX	21K0278JZX
10CN10R	10CN10R 10.0MM ADT FLEX TRACH W TG CUFF	10884521205475	202107218X	202108128X	21H0792JZX	21H0793JZX	21H0794JZX	22I0596JZX
			202107296X	202108285X				
10UN10A	10UN10A 10.0MM UNCUFF TRACH TUBE X1	20884521175690	21D0463JZX					
10UN10H	10UN10H 10.0MM SHILEY CUFFLESS TRACH C	20884521176291	21E0661JZX	21G0473JZX				
10UN10R	10UN10R 10.0MM ADT FLEX TRACH CUFFLESS	10884521205543	202105307X	202105308X	202106148X	202209335X		
4CN65A	4CN65A 6.5MM TRACH TUBE W TG CUFF X1	10884521172456	21C0432JZX	21I0369JZX				
4CN65H	4CN65H 6.5MM SHILEY CUFFED TRACH CANN	20884521176307	21C0358JZX	21E0519JZX	21E1777JZX	21K0643JZX	22D0898JZX	22F0926JZX
			21C0359JZX	21E0520JZX	21E1778JZX	21K0645JZX	22D0899JZX	22F0927JZX
			21C0360JZX	21E0521JZX	21E1779JZX	22C1465JZX	22D0900JZX	22F0928JZX
			21C0361JZX	21E0522JZX	21E1780JZX	22C1466JZX	22D0901JZX	22F0929JZX
			21D0440JZX	21E0523JZX	21E1781JZX	22C1467JZX	22D0909JZX	22J0073JZX
			21D0441JZX	21E0524JZX	21E1782JZX	22D0798JZX	22F0918JZX	22J0074JZX
			21E0512JZX	21E0525JZX	21E1783JZX	22D0799JZX	22F0919JZX	22J0075JZX
			21E0513JZX	21E0526JZX	21H1324JZX	22D0800JZX	22F0920JZX	22J0076JZX
			21E0514JZX	21E0527JZX	21J0181JZX	22D0801JZX	22F0921JZX	22J0077JZX
			21E0515JZX	21E1773JZX	21J1094JZX	22D0891JZX	22F0922JZX	22J0080JZX
			21E0516JZX	21E1774JZX	21K0237JZX	22D0892JZX	22F0923JZX	22J0081JZX
			21E0517JZX	21E1775JZX	21K0239JZX	22D0893JZX	22F0924JZX	22J0083JZX
4CN65R	4CN65R 6.5MM ADT FLEX TRACH W TG CUFF X1	10884521205024	202105082X	202106267X	202107294X	202111088X	202111399X	202201303X
			202105310X	202106268X	202107295X	202111270X	202112135X	202202186X
4UN65A	4UN65A 6.5MM UNCUFF TRACH TUBE X1	20884521175706	21D0466JZX	21E0659JZX	21E0660JZX			
4UN65H	4UN65H 6.5MM SHILEY CUFFLESS TRACH CA	20884521176239	21C0413JZX	21C0417JZX	21D0900JZX	21E1785JZX	22D0932JZX	22E0679JZX
			21C0414JZX	21D0898JZX	21D0901JZX	22D0930JZX	22D0933JZX	22E0680JZX
			21C0416JZX	21D0899JZX	21E1784JZX	22D0931JZX		
4UN65R	4UN65R 6.5MM ADT FLEX TRACH CUFFLESSX1	10884521205482	202107297X	202107300X	202108123X	202108125X	202108140X	202108229X
			202107298X	202108122X	202108124X	202108139X	202108228X	21E1139JZX
			202107299X					
5CN70A	5CN70A 7.0MM TRACH TUBE W TG CUFF X1	10884521172463	22D0927JZX	22D0929JZX	22H0032JZX	22H0860JZX	22H0863JZX	22J0071JZX
			22D0928JZX	22H0031JZX	22H0033JZX	22H0861JZX	22H0865JZX	22J0072JZX
5CN70H	5CN70H 7.0MM SHILEY CUFFED TRACH CANN	20884521176314	21C0404JZX	21G1130JZX	21I0286JZX	21I0522JZX	21I0630JZX	22D0926JZX
			21C0405JZX	21I0283JZX	21I0519JZX	21I0544JZX	21I0631JZX	22H0152JZX
			21C0406JZX	21I0284JZX	21I0520JZX	21I0545JZX	22D0924JZX	
			21D0462JZX	21I0285JZX	21I0521JZX	21I0546JZX	22D0925JZX	
5CN70R	5CN70R 7.0MM ADT FLEX TRACH W TG CUFF X1	10884521205420	202111135X	202208294X	202208295X	202210208X		

Item Code/ Model Number	Product Description	GTIN	Affected Lot Numbers					
5UN70A	5UN70A 7.0MM UNCUFF TRACH TUBE X1	20884521175713	21B0062JZX	21E0645JZX	21E0646JZX	21E0647JZX		
5UN70H	5UN70H 7.0MM SHILEY CUFFLESS TRACH CA	20884521176246	21E0655JZX	21E0656JZX	21G1008JZX	21G1009JZX	21H0735JZX	
5UN70R	5UN70R 7.0MM ADT FLEX TRACH CUFFLESSX1	10884521205499	202208296X					
6CN75A	6CN75A 7.5MM TRACH TUBE W TG CUFF X1	10884521172470	22A0137JZX	22H0868JZX				
6CN75H	6CN75H 7.5MM SHILEY CUFFED TRACH CANN	20884521176321	21D0420JZX	21E1673JZX	21I0267JZX	21L0810JZX	22B0336JZX	22G0414JZX
			21D0421JZX	21E1674JZX	21I0268JZX	21L0811JZX	22B0337JZX	22G0420JZX
			21D0422JZX	21E1675JZX	21I0269JZX	21L0812JZX	22C0758JZX	22H0872JZX
			21D0423JZX	21E1676JZX	21I0270JZX	21L0813JZX	22C0759JZX	22H0873JZX
			21D0424JZX	21E1677JZX	21I0271JZX	21L0814JZX	22D0936JZX	22H0874JZX
			21D0425JZX	21E1678JZX	21I0491JZX	21L0815JZX	22D0937JZX	22H0875JZX
			21D0426JZX	21E1679JZX	21I0492JZX	21L0816JZX	22D0938JZX	22H0877JZX
			21D0427JZX	21E1680JZX	21I0680JZX	21L0817JZX	22D0939JZX	22H0881JZX
			21D0428JZX	21E1681JZX	21I0681JZX	21L0818JZX	22D0940JZX	22H0886JZX
			21D0429JZX	21E1682JZX	21I0682JZX	21L0819JZX	22D0941JZX	22H0887JZX
			21D0430JZX	21E1683JZX	21I0683JZX	22A0665JZX	22D0942JZX	22J0084JZX
			21D0431JZX	21E1684JZX	21J0090JZX	22A0666JZX	22D0943JZX	22J0085JZX
			21D0432JZX	21E1685JZX	21J0168JZX	22A0670JZX	22D0944JZX	22J0086JZX
			21D0433JZX	21E1686JZX	21J0169JZX	22A0671JZX	22D0945JZX	22J0093JZX
			21D0434JZX	21E1687JZX	21J0170JZX	22A0672JZX	22D0946JZX	22J0094JZX
			21D0435JZX	21E1688JZX	21J0171JZX	22A0673JZX	22D0947JZX	22J0095JZX
			21D0436JZX	21E1689JZX	21J0172JZX	22A0674JZX	22D0948JZX	22J0096JZX
			21D0437JZX	21E1690JZX	21J0176JZX	22A0771JZX	22D0951JZX	22J0097JZX
			21D0438JZX	21E1691JZX	21J0177JZX	22A0772JZX	22D0952JZX	22J0098JZX
			21D0439JZX	21E1694JZX	21J1088JZX	22A0900JZX	22D0953JZX	22J0099JZX
			21D0741JZX	21E1695JZX	21J1410JZX	22A0901JZX	22D0954JZX	22J0100JZX
			21D0742JZX	21E1696JZX	21J1411JZX	22A0902JZX	22D0955JZX	22J0101JZX
			21D0743JZX	21E1697JZX	21J1417JZX	22A0903JZX	22D0956JZX	22J0102JZX
			21D0744JZX	21E1769JZX	21J1418JZX	22A0904JZX	22D0957JZX	22J0103JZX
			21D0745JZX	21F0692JZX	21L0549JZX	22A0905JZX	22D0958JZX	22J0104JZX
			21D0746JZX	21F0693JZX	21L0550JZX	22A0906JZX	22D0960JZX	22J0187JZX
			21D0747JZX	21F0694JZX	21L0551JZX	22A0907JZX	22D0961JZX	22J0189JZX
			21D0748JZX	21G0296JZX	21L0552JZX	22A0908JZX	22D0962JZX	22J0190JZX
			21D0749JZX	21G0297JZX	21L0553JZX	22A0909JZX	22D0963JZX	22J0191JZX
			21E0632JZX	21G0298JZX	21L0756JZX	22A0910JZX	22D0964JZX	22J0192JZX
			21E0633JZX	21G0299JZX	21L0777JZX	22A0911JZX	22D0965JZX	22J0193JZX
			21E0634JZX	21G0426JZX	21L0778JZX	22A0912JZX	22D0966JZX	22J0194JZX
			21E0635JZX	21G0427JZX	21L0779JZX	22A0913JZX	22D0967JZX	22J0196JZX
			21E0636JZX	21G0428JZX	21L0796JZX	22A0914JZX	22D0968JZX	22J0197JZX
			21E0637JZX	21G0429JZX	21L0797JZX	22A0915JZX	22D0969JZX	22J0198JZX
			21E0638JZX	21G0430JZX	21L0801JZX	22A0916JZX	22D0970JZX	22J0206JZX
			21E0639JZX	21H0624JZX	21L0802JZX	22B0277JZX	22D0971JZX	22K0244JZX
			21E0640JZX	21I0260JZX	21L0803JZX	22B0280JZX	22D0972JZX	22K1921JZX
			21E0641JZX	21I0261JZX	21L0804JZX	22B0288JZX	22G0403JZX	22K1922JZX
			21E0642JZX	21I0262JZX	21L0805JZX	22B0289JZX	22G0404JZX	22K1983JZX

Item Code/ Model Number	Product Description	GTIN	Affected Lot Numbers					
			21E0643JZX	21I0263JZX	21L0806JZX	22B0290JZX	22G0405JZX	
			21E0644JZX	21I0264JZX	21L0807JZX	22B0291JZX	22G0406JZX	
			21E1100JZX	21I0265JZX	21L0808JZX	22B0334JZX	22G0407JZX	
			21E1101JZX	21I0266JZX	21L0809JZX	22B0335JZX	22G0408JZX	
6CN75R	6CN75R 7.5MM ADT FLEX TRACH W TG CUFF X1	10884521205437	202110171X	202203160X	202204167X	202207266X	202209220X	21G0482JZX
			202110231X	202203304X	202206076X	202207267X	202210429X	21L0522JZX
			202110310X	202203305X	202206077X	202207268X	21G0479JZX	21L0523JZX
			202110387X	202203306X	202206078X	202208201X	21G0480JZX	21L0524JZX
			202111268X	202203406X	202207117X	202208202X	21G0481JZX	21L0526JZX
6UN75H	6UN75H 7.5MM SHILEY CUFFLESS TRACH CA	20884521176253	21C0420JZX	21E1765JZX	22B1043JZX	22D0792JZX	22D0921JZX	22K0257JZX
			21C0421JZX	21E1766JZX	22B1044JZX	22D0793JZX	22D0922JZX	22K0258JZX
			21C0422JZX	21E1767JZX	22B1045JZX	22D0794JZX	22E1002JZX	22K0259JZX
			21C0423JZX	21F0225JZX	22B1046JZX	22D0795JZX	22E1003JZX	22K0260JZX
			21C0424JZX	21G1158JZX	22B1047JZX	22D0796JZX	22E1004JZX	22K0261JZX
			21C0425JZX	21G1160JZX	22B1048JZX	22D0902JZX	22E1005JZX	22K0262JZX
			21C0426JZX	21G1161JZX	22B1049JZX	22D0903JZX	22E1008JZX	22K0263JZX
			21C0427JZX	21G1162JZX	22B1052JZX	22D0904JZX	22E1009JZX	22K0264JZX
			21C0428JZX	21G1163JZX	22B1053JZX	22D0905JZX	22E1010JZX	22K0265JZX
			21C0429JZX	21H0749JZX	22B1054JZX	22D0906JZX	22E1012JZX	22K0267JZX
			21C0430JZX	21H1009JZX	22C1511JZX	22D0907JZX	22E1013JZX	22K0268JZX
			21E1758JZX	21I0022JZX	22C1512JZX	22D0908JZX	22E1014JZX	22K0269JZX
			21E1759JZX	22B1035JZX	22C1513JZX	22D0913JZX	22E1015JZX	22K0270JZX
			21E1760JZX	22B1036JZX	22C1514JZX	22D0914JZX	22E1016JZX	22K0271JZX
			21E1761JZX	22B1039JZX	22C1515JZX	22D0915JZX	22E1017JZX	22K0272JZX
			21E1762JZX	22B1040JZX	22C1516JZX	22D0916JZX	22K0254JZX	22K0273JZX
			21E1763JZX	22B1041JZX	22C1518JZX	22D0919JZX	22K0255JZX	22K0274JZX
21E1764JZX	22B1042JZX	22C1519JZX	22D0920JZX	22K0256JZX	22K0275JZX			
6UN75R	6UN75R 7.5MM ADT FLEX TRACH CUFFLESSX1	10884521205505	202107305X	202109214X	202111266X	22C1156JZX	22E1001JZX	22H0069JZX
			202107306X	202109215X	202201019X	22C1157JZX	22H0064JZX	22H0072JZX
			202108126X	202109340X	21G0487JZX	22C1158JZX	22H0065JZX	22H0073JZX
			202108178X	202111221X	21H0958JZX	22C1159JZX	22H0067JZX	22H0075JZX
			202108179X	202111222X	22B0728JZX	22C1160JZX	22H0068JZX	22H0076JZX
7CN80A	7CN80A 8.0MM TRACH TUBE W TG CUFF X1	10884521172487	21C0355JZX	22D0975JZX	22D0976JZX	22E0964JZX		
7CN80H	7CN80H 8.0MM SHILEY CUFFED TRACH CANN	20884521176338	21C0381JZX	21C0384JZX	21E1698JZX	21I0402JZX	21K0652JZX	21K0654JZX
			21C0382JZX	21D0442JZX	21G0454JZX	21K0651JZX	21K0653JZX	21K0655JZX
			21C0383JZX	21D0443JZX				
7CN80R	7CN80R 8.0MM ADT FLEX TRACH W TG CUFF X1	10884521205444	202104382X	202105284X	202203162X	202204065X	202206208X	202206297X
			202104383X	202106225X	202203309X	202206207X	202206209X	21G0791JZX
			202105228X					
7UN80A	7UN80A 8.0MM UNCUFF TRACH TUBE X1	20884521175737	20J0050JZX	21C0356JZX	21E1744JZX	22C0313JZX	22C0314JZX	
7UN80H	7UN80H 8.0MM SHILEY CUFFLESS TRACH CA	20884521176260	21C0431JZX	21E1768JZX	22C1527JZX	22C1528JZX		
7UN80R	7UN80R 8.0MM ADT FLEX TRACH CUFFLESSX1	10884521205512	202203307X	21G0774JZX				
8CN85A		10884521172494	21C0434JZX	21C0436JZX	21I0366JZX	22E1151JZX	22E1156JZX	22E1157JZX

Item Code/ Model Number	Product Description	GTIN	Affected Lot Numbers					
8CN85H	8CN85A 8.5MM TRACH TUBE W TG CUFF X1	20884521176345	21C0435JZX	21I0287JZX	22A0136JZX	22E1152JZX		
			21C0386JZX	21E1094JZX	21G0291JZX	22A0828JZX	22E1264JZX	22F0899JZX
			21C0387JZX	21E1095JZX	21G1149JZX	22A0829JZX	22E1265JZX	22F0900JZX
			21C0388JZX	21E1142JZX	21G1150JZX	22A0830JZX	22E1266JZX	22I0530JZX
			21C0389JZX	21E1143JZX	21H0796JZX	22A0831JZX	22E1267JZX	22I0531JZX
			21C0390JZX	21E1146JZX	21H0797JZX	22A0832JZX	22F0476JZX	22I0532JZX
			21C0391JZX	21E1147JZX	21I0330JZX	22A0833JZX	22F0477JZX	22I0533JZX
			21C0392JZX	21E1550JZX	21I0331JZX	22A0835JZX	22F0478JZX	22I0534JZX
			21C0393JZX	21E1551JZX	21I0332JZX	22A0836JZX	22F0479JZX	22J0120JZX
			21C0394JZX	21E1552JZX	21I0333JZX	22C0795JZX	22F0480JZX	22J0121JZX
			21C0395JZX	21E1711JZX	21I0334JZX	22C0797JZX	22F0481JZX	22J0122JZX
			21C0396JZX	21E1714JZX	21I0367JZX	22C0798JZX	22F0482JZX	22J0123JZX
			21C0397JZX	21E1715JZX	21I0368JZX	22C0799JZX	22F0483JZX	22J0124JZX
			21C0398JZX	21E1716JZX	21J0186JZX	22C0800JZX	22F0484JZX	22J0125JZX
			21C0399JZX	21E1717JZX	21J0187JZX	22C0802JZX	22F0485JZX	22J0126JZX
			21C0400JZX	21E1718JZX	21J0188JZX	22C0813JZX	22F0486JZX	22J0127JZX
			21C0401JZX	21E1719JZX	21J0189JZX	22C0814JZX	22F0487JZX	22J0128JZX
			21D0444JZX	21E1720JZX	21J0190JZX	22C0815JZX	22F0488JZX	22J0129JZX
			21D0445JZX	21E1721JZX	21J0191JZX	22C0819JZX	22F0489JZX	22J0130JZX
			21D0446JZX	21E1722JZX	21J0193JZX	22C0820JZX	22F0490JZX	22J0131JZX
			21D0447JZX	21E1723JZX	21I0333JZX	22E1231JZX	22F0491JZX	22J0132JZX
			21D0448JZX	21E1724JZX	22A0694JZX	22E1232JZX	22F0492JZX	22J1084JZX
			21D0449JZX	21E1725JZX	22A0695JZX	22E1233JZX	22F0493JZX	22J1085JZX
			21D0450JZX	21E1726JZX	22A0779JZX	22E1234JZX	22F0494JZX	22J1096JZX
			21D0451JZX	21E1727JZX	22A0780JZX	22E1235JZX	22F0495JZX	22J1097JZX
			21D0452JZX	21E1728JZX	22A0781JZX	22E1236JZX	22F0496JZX	22J1098JZX
			21D0453JZX	21E1729JZX	22A0782JZX	22E1237JZX	22F0497JZX	22J1099JZX
			21D0454JZX	21E1730JZX	22A0783JZX	22E1238JZX	22F0498JZX	22J1100JZX
			21D0455JZX	21E1731JZX	22A0784JZX	22E1239JZX	22F0499JZX	22J1101JZX
			21D0456JZX	21E1732JZX	22A0785JZX	22E1240JZX	22F0500JZX	22J1102JZX
			21D0457JZX	21E1733JZX	22A0786JZX	22E1243JZX	22F0501JZX	22J1103JZX
			21D0460JZX	21E1734JZX	22A0787JZX	22E1244JZX	22F0502JZX	22J1104JZX
			21E0623JZX	21E1735JZX	22A0788JZX	22E1245JZX	22F0503JZX	22J1105JZX
			21E0624JZX	21E1736JZX	22A0820JZX	22E1246JZX	22F0504JZX	22J1107JZX
			21E0625JZX	21E1737JZX	22A0821JZX	22E1247JZX	22F0505JZX	22J1108JZX
			21E0626JZX	21E1738JZX	22A0822JZX	22E1248JZX	22F0506JZX	22J1109JZX
			21E0627JZX	21F0524JZX	22A0823JZX	22E1249JZX	22F0862JZX	22J1115JZX
			21E0628JZX	21G0287JZX	22A0824JZX	22E1260JZX	22F0863JZX	
			21E0629JZX	21G0288JZX	22A0825JZX	22E1261JZX	22F0864JZX	
			21E0630JZX	21G0289JZX	22A0826JZX	22E1262JZX	22F0897JZX	
			21E0631JZX	21G0290JZX	22A0827JZX	22E1263JZX	22F0898JZX	
8CN85R	8CN85R 8.5MM ADT FLEX TRACH W TG CUFF X1	10884521205451	202106382X	202109124X	202111115X	202202323X	21H0764JZX	21J0383JZX
			202107194X	202109168X	202201302X	202202438X	21H0795JZX	22A0732JZX
			202107195X	202110189X	202202117X	202204062X	21H0951JZX	22F0889JZX
			202107196X	202111087X	202202118X	21H0762JZX	21H0952JZX	22H0040JZX
			202109037X	202111106X	202202120X	21H0763JZX	21J0382JZX	

Item Code/ Model Number	Product Description	GTIN	Affected Lot Numbers						
8UN85A	8UN85A 8.5MM UNCUFF TRACH TUBE X1	20884521175744	22C1488JZX						
8UN85H	8UN85H 8.5MM SHILEY CUFFLESS TRACH CA	20884521176277	21C0408JZX	21E1746JZX	21E1751JZX	21L0296JZX	21L0301JZX	21L0380JZX	
			21C0409JZX	21E1747JZX	21E1752JZX	21L0297JZX	21L0302JZX	22B1059JZX	
			21C0410JZX	21E1748JZX	21E1753JZX	21L0298JZX	21L0303JZX	22B1060JZX	
			21E0653JZX	21E1749JZX	21F0523JZX	21L0299JZX	21L0304JZX	22C1484JZX	
			21E0654JZX	21E1750JZX	21H0479JZX	21L0300JZX	21L0305JZX	22C1485JZX	
			21E1745JZX						
8UN85R	8UN85R 8.5MM ADT FLEX TRACH CUFFLESSX1	10884521205529	202105199X	202106264X	202107063X	202107115X	202108188X	202208021X	
			202105200X	202106265X	202107064X	202107116X	202108230X	202209336X	
			202105201X	202106313X	202107065X	202107202X	202202326X	21G0922JZX	
			202105383X	202106314X	202107113X	202108121X	202203066X	22C1430JZX	
			202105384X	202106315X	202107114X	202108187X	202203409X	22C1432JZX	
			202105385X	202106316X					
9CN90H	9CN90H 9.0MM SHILEY CUFFED TRACH CANN	20884521176352	21C0411JZX	21D0464JZX	21D0601JZX	21I0556JZX	21K0262JZX	21K0263JZX	
			21C0412JZX	21D0465JZX	21I0555JZX				
9CN90R	9CN90R 9.0MM ADT FLEX TRACH W TG CUFF X1	10884521205468	202105281X	202110114X	202202327X	202204166X	202205514X		
9UN90H	9UN90H 9.0MM SHILEY CUFFLESS TRACH CA	20884521176284	21E0657JZX	21E0658JZX					
9UN90R	9UN90R 9.0MM ADT FLEX TRACH CUFFLESSX1	10884521205536	202203308X	21F0328JZX					

Customer Confirmation Form
Urgent Medical Device Recall

Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff, and Cuffless: Disposable Inner Cannula or Reusable Inner Cannula

Refer to Attachment B of Customer Communication for model number and affected lot number

For completion by Medtronic Customers Only - Please complete all fields below and return all pages immediately, even if you do not have any product to return.

By signing this form, I confirm that I have read the Urgent Medical Device Recall Notification Letter dated 27-March-2023, from Medtronic regarding Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff and Cuffless: Disposable Inner Cannula or Reusable Inner Cannula and taken appropriate action.

Please complete and sign the form as indicated below and email to rs.canfieldactions@medtronic.com.

Name of person completing form

Hospital/Account Name

Title/Department

Hospital/Account Address

Email

Hospital/Account City, Province, Postal Code

Phone number

Signature (in ink)

Date (DD-MMM-YYYY)

No inventory to return - (please check):

Please fill-in below the quantity of product that you have in your existing stock and will be returning.

Product Number/CFN	Lot Number	Qty On-hand to return (units)

Product Number/CFN	Lot Number	Qty on-hand to return (units)

Return Instructions:

- Identify and quarantine all unused affected Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff and Cuffless: Disposable Inner Cannula or Reusable Inner Cannula above.
- Product purchased directly from Medtronic please send your completed form to rs.canfieldactions@medtronic.com for a Returned Goods Authorization (RGA).
- Credit for the returned affected product will be issued based on the RGA number. Customers can place orders for replacement product at the time the RGA is issued.
- If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.

Note: The addressee may continue to receive reminders of this notice until a response is received.

For questions, contact your Medtronic Representative.